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Patent
239/227

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 239/227
First Named Inventor: Farhad Khosravi, et al
Prior Application Information:
Examiner: Not yet assigned
Art Unit: Not yet assigned

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D. C. 20231

FILING UNDER 37 CFR § 1.53(B)

This is a request for filing for a

☐ continuation ☐ divisional ☒ continuation-in-part (CIP)

application under 37 CFR § 1.53(b) of pending prior application Serial
No. 09/192,977 filed on November 16, 1998.

entitled: STRETCHABLE ANTI-BUCKLING COILED-SHEET STENT

For CONTINUATION or DIVISION APPS only: The entire disclosure of the prior application,
from which an oath or declaration is supplied under Box 4b, is considered a part of the
disclosure of the accompanying continuation or divisional application and is hereby
incorporated by reference. The incorporation can only be relied upon when a portion has been
inadvertently omitted from the submitted application parts.

35 Page(s) of Written Description
13 Page(s) of Claims
2 Page(s) of Abstract
28 Sheet(s) of Drawings ☐ formal ☒ informal
2 Page(s) of ☒ Declaration or ☐ Declaration and Power of Attorney
☒ Small Entity Statement

CERTIFICATE OF MAILING
(37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with
the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To
Addressee' in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

EL267173860
Express Mail Label No.

October 25, 1999
Date of Deposit

SALLY HARTWELL
Name of Person Mailing Paper

Sally Hartwell
Signature of Person Mailing Paper

- ☐ Pursuant to 37 § CFR 1.63(d)(1), a newly executed oath or declaration is not required.
- ☒ A newly executed oath or declaration is filed herewith
- ☐ I hereby state that the amendment referred to in the declaration filed to complete the prior application, in accordance with the requirements of 37 CFR § 1.53(b), did not introduce new matter therein.

I. AMENDMENTS

- ☐ Cancel in this application original Claims _____ of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
- ☐ A Preliminary Amendment is enclosed. (Claims added by Amendment must be numbered consecutively beginning with the number next following the highest numbered original claim in the prior application.)

II. INFORMATION DISCLOSURE STATEMENT

- ☒ An Information Disclosure Statement, PTO 1449, and copies of citations are submitted herewith.

III. PETITION FOR SUSPENSION OF PROSECUTION FOR THE TIME TO FILE AN AMENDMENT

- ☐ Filed herewith under separate cover is a petition for suspension of prosecution under 37 CFR § 1.103, together with the fee due under 37 CFR § 1.17 (h).

IV. FEE CALCULATION

BASIC FILING FEE:							\$760.00
Total Claims	50	-	20	=	30	x \$18.00	\$540.00
Independent Claims	5	-	3	=	2	x \$78.00	\$156.00
Multiple Dependent Claims	\$260	(if applicable)				<input type="checkbox"/>	\$0.00
TOTAL OF ABOVE CALCULATIONS							\$1,456.00
Reduction by ½ for Filing by Small Entity. Note 37 CFR §§ 1.9, 1.27, 1.28. If applicable, Verified Statement must be attached.							<input checked="" type="checkbox"/> \$728.00
Misc. Filing Fees (Recordation of Assignment)							\$40.00
TOTAL FEES SUBMITTED HERewith							\$768.00

V. SMALL ENTITY STATUS

A Verified Statement to establish small entity under 37 CFR §§ 1.9 and 1.27:

- ☒ is attached.
- ☐ has been filed in the prior application and such status is still proper and desired.
[37 CFR § 1.28(a)]

VI. DRAWINGS

[NOTE: DO NOT CHECK THIS IF PRIOR CASE IS NOT TO BE ABANDONED.]

- ☐ Transfer the drawings from the prior application to this application and, subject to Item 16 below, abandon said prior application as of the filing date accorded to this application. A duplicate copy of this request is enclosed for filing in the prior application file.
[May only be used if signed by (1) applicant, (2) assignee of record or (3) attorney or agent of record and before payment of issue fee. 37 CFR § 1.138.]
- ☐ Transfer the following sheet(s) of drawings from the prior application to this application.
- ☒ New drawings are enclosed ☐ formal ☒ informal

VII. PRIORITY - 35 USC § 119

- ☐ Priority of application Serial No. _____ filed on _____ in Country is claimed under 35 USC § 119.
- ☐ The certified copy has been filed in prior U.S. application Serial No. _____ on _____.
- ☐ The certified copy will follow.

VIII. RELATE BACK - 35 USC § 120

- ☒ Amend the Specification by inserting before the first line the sentence:
This is a continuation-in-part of co-pending application Serial No. 09/192,977
filed November 16, 1998.
- ☐ Relate back information included in preliminary amendment or specification.

IX. INVENTORSHIP STATEMENT

- ☒ With respect to the prior co-pending U.S. application from which this application claims benefit under 35 USC § 120, the inventor(s) in this application is (are):
- ☒ the same
- ☐ less than those named in the prior application and it is requested that the following inventor(s) identified above for the prior application be deleted:

[Name(s) of inventor(s) to be deleted]

- ☒ The inventorship for all the claims in this application is:
- ☒ the same.
- ☐ not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

X. ASSIGNMENT

- ☒ The prior application is assigned of record to Endotex Interventional Systems, Inc.
- ☒ An Assignment of the invention to Endotex Interventional Systems, Inc. is attached.

XI. FEE PAYMENT BEING MADE AT THIS TIME

- ☐ Not attached. No filing fee is submitted. [This and the surcharge required by 37 CFR § 1.16(e) can be paid subsequently.]

☒ Attached.

- | | | |
|-------------------------------------|--|-----------------|
| <input checked="" type="checkbox"/> | Filing fees. | <u>\$728.00</u> |
| <input type="checkbox"/> | Recording assignment. [\$40.00 37 CFR § 1.21(h)(1)] | <u>\$40.00</u> |
| | Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached.
[\$130.00; 37 CFR §§ 1.47 and 1.17(h)] | |
| <input type="checkbox"/> | Petition fee to Suspend Prosecution for the Time Necessary to File an Amendment (New Application Filed Concurrently.) | — |
| | [\$130.00; 37 CFR §§ 1.103 and 1.17(i)] | |
| <input type="checkbox"/> | For processing an application with a specification in a non-English language. | — |
| | [\$130.00; 37 CFR §§ 1.52(d) and 1.17(k)] | |
| <input type="checkbox"/> | Processing and retention fee. | — |
| | [\$130.00; 37 CFR §§ 1.53(f) and 1.21(l)] | |

Total Fees Enclosed \$768.00

XII. METHOD OF PAYMENT OF FEES

- ☒ Attached is a check in the amount of \$768.00.
- ☐ Charge Lyon & Lyon's Deposit Account No. **12-2475** in the amount of _____.

XIII. AUTHORIZATION TO CHARGE ADDITIONAL FEES

The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Deposit Account No. **12-2475**:

- ☒ 37 CFR § 1.16(a) (filing fees)
- ☒ 37 CFR § 1.16(b) (presentation of extra claims)
- ☐ 37 CFR § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☒ 37 CFR § 1.17 (application processing fees)
- ☐ 37 CFR § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR § 1.311(b))

XIV. INSTRUCTIONS AS TO OVERPAYMENT

- ☒ Credit Lyon & Lyon's Deposit Account No. **12-2475**
- ☐ Refund check

XV. POWER OF ATTORNEY

- ☒ The power of attorney in the prior application is to Lyon & Lyon LLP.
- ☒ The power of attorney in the prior application is to the registered attorneys and/or agents listed below and members of or associates in the law firm of **LYON & LYON LLP**, 633 West Fifth Street, 47th Floor, Los Angeles, California 90071, Registration No. 11,611, whose members are registered to practice in the U.S. Patent and Trademark office:

Roland N. Smoot, Reg. No. 18,718
Conrad R. Solum, Jr., Reg. No. 20,467
James W. Geriak, Reg. No. 20,233
Robert M. Taylor, Jr., Reg. No. 19,848
Samuel B. Stone, Reg. No. 19,297
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Robert E. Lyon, Reg. No. 24,171
Robert C. Weiss, Reg. No. 24,939
Richard E. Lyon, Jr., Reg. No. 26,300
John D. McConaghy, Reg. No. 26,733
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F. T. Alexandra Mahaney, Reg. No. 37,668
Stephen S. Korniczky, Reg. No. 34,853
James P. Brogan, Reg. No. 35,833
David A. Randall, Reg. No. 37,217
Christopher A. Vanderlaan, Reg. No. 37,747

- ☒ The power appears in the original papers in the prior application.
- ☐ The power does not appear in the original papers, but was filed on _____ in this application.
- ☒ A new power has been executed and is attached.
- ☒ Address all future communications to:

LYON & LYON LLP
633 West Fifth Street, 47th Floor
Los Angeles, California 90071
(714) 751-6606
Attention: William A. English

XVI. MAINTENANCE OF CO-PENDENCY OF PRIOR APPLICATION

- ☐ A petition, fee and response has been filed to extend the term in the pending **prior** application until _____. A copy of the petition for extension of time in the **prior** application is attached.
- ☐ A conditional petition for extension of time is being filed in the pending **prior** application. A copy of the conditional petition for extension of time in the **prior** application is attached.

XVII. ABANDONMENT OF PRIOR APPLICATION

- ☐ Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application co-pending with said prior application. At the same time, please add the words "now abandoned" to the amendment of the specification set forth in Item IX above.

Respectfully submitted,

LYON & LYON LLP



William A. English
Reg. No. 42,515

Dated: October 25, 1999

633 West Fifth Street, Suite 4700
Los Angeles, California 90071-2066
(714) 751-6606

Enclosures

Applicant or Patentee: FARHAD KHOSRAVI and HIMANSHU N. PATEL
Serial or Patent No.: Not Yet Assigned
Filed or Issued: Herewith
For: STRETCHABLE ANTI-BUCKLING COILED-SHEET STENT

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- ☒ the owner of the small business concern identified below:
- ☐ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN ENDOTEX INTERVENTIONAL SYSTEMS, INC.

ADDRESS OF CONCERN 10231 Bubb Road, Cupertino, CA 95014

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed, to and remain with the small business concern identified above with regard to the invention, entitled

STRETCHABLE ANTI-BUCKLING COILED-SHEET STENT

by inventor(s) FARHAD KHOSRAVI and HIMANSHU N. PATEL

described in

- ☒ the specification filed herewith
- ☐ the application serial no. _____, filed _____
- ☐ patent no. _____, issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME n/a

ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

NAME n/a

ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small business entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING JOHN MARONEY

TITLE OF PERSON SIGNING President

ADDRESS OF PERSON SIGNING 10231 Bubb Road, Cupertino, CA 95014

SIGNATURE  DATE 10/2/2012 JMM

655207 0322460

DESCRIPTION

STRETCHABLE ANTI-BUCKLING COILED-SHEET STENT

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FIELD OF THE INVENTION

The present invention relates generally to prostheses for implantation within body lumens, and more particularly to a coiled-sheet stent including one or more stretchable regions.

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BACKGROUND

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Tubular prostheses or "stents" are often implanted within blood vessels, for example, within the coronary and carotid arteries, for treating atherosclerotic disease which may involve one or more stenoses. Stents generally have a tubular shape capable of assuming a radially contracted condition to facilitate introduction into a patient's vasculature, and an enlarged condition for engaging the vessel wall at a treatment location. In its contracted condition, the stent may be placed on or in a delivery device, such as a catheter, percutaneously introduced into a patient's vasculature and advanced to a target treatment location. Once at the treatment location, the stent may be deployed and expanded to its enlarged condition, thereby engaging the wall of the vessel and substantially anchoring the stent in place.

Plastically deformable stents have been suggested that are initially provided in their contracted condition, and placed over a balloon on an angioplasty catheter. At the treatment location, the balloon is inflated to plastically deform the stent until it is expanded to its enlarged condition. Thus, the stent may be expanded to any size within a specified range to ensure that the stent substantially engages the wall of the vessel. Plastically deformable stents, however, may not expand uniformly and may not provide a desired delivery profile because of the need for a balloon on the delivery device underlying the stent.

Stents have also been suggested that are self-expanding or elastically deformable, i.e., that are biased to assume their enlarged condition but may be radially compressed to a contracted condition. The stent may be mounted to a delivery device and constrained in its contracted condition during delivery, for example, by an overlying sheath. At the treatment location, the stent may be released, for example, by retracting the overlying sheath, the stent automatically resuming its enlarged condition to engage the vessel wall. Such stents, however, may not provide as small a delivery profile as desired and may not anchor against the wall of a vessel as securely as desired, which may lead to migration of the stent within the vessel.

In addition to tubular stents, coiled-sheet stents have been suggested. A flat sheet is provided that is rolled into a spiral shape having overlapping inner and outer longitudinal sections that defines a contracted condition. The coiled-up sheet may be
5 biased to at least partially unroll to assume an enlarged condition, and/or may be caused to unroll and radially expand using a balloon. The coiled-sheet stent may have a nondeformable lattice-like structure and a plurality of fingers or teeth along the inner longitudinal section for engaging openings in the
10 lattice.

Once the coiled-sheet stent is deployed at the treatment location and at least partially expands, a balloon may be introduced within the stent and inflated to further expand the stent to a desired enlarged condition. When the balloon is
15 deflated, the stent may try to radially contract, but the fingers on the inner longitudinal section may then engage corresponding openings in the lattice to lock the stent in the enlarged condition.

Coiled-sheet stents may provide enhanced anchoring within
20 the blood vessel because the size of the fully expanded stent may be more precisely controlled. A coiled-sheet stent, however, may be more rigid transverse to its longitudinal axis than tubular

stents, potentially resulting in a less flexible stent, which may not be implanted as effectively in tortuous anatomical conditions. Further, because the lattice-like structure of coiled-sheet stents is substantially nondeformable, if the stent is subjected to radially compressive forces, e.g., when the vessel wall attempts to contract, the stent may tend to buckle rather than recoil from the stress.

Accordingly, there is a need for a stent that provides improved flexibility, while still providing substantial anchoring within a blood vessel.

SUMMARY OF THE INVENTION

The present invention is directed to coiled-sheet stents having stretchable regions, preferably having programmed shape memories, and to methods for making and using such stents. In accordance with one aspect of the present invention, a stretchable stent is provided that includes a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof. The coiled-up sheet is expandable between a contracted condition and one or more enlarged conditions. A plurality of stretchable elements are formed in the coiled-up sheet, the stretchable

elements being expandable between an unstretched condition and a stretched condition.

In a preferred form, the coiled-up sheet may be at least partially biased to expand from the contracted condition towards the one or more enlarged conditions. The stretchable elements may be biased to assume the stretched condition, thereby at least partially biasing the coiled-up sheet to radially expand from the contracted condition towards the one or more enlarged conditions.

More preferably, the coiled-up sheet may be formed from a material having a temperature-based shape memory, whereby the stretchable elements are biased towards the unstretched condition when exposed to a first temperature and towards the stretched condition when exposed to a second temperature. Preferably, the second temperature is at or above body temperature, and the first temperature is at or below about 25 degrees Celsius. Even more preferably, the coiled-up sheet is formed from Nitinol such that the Nitinol is substantially in its martensitic phase at the first temperature and substantially in its austenitic phase at the second temperature.

In alternative forms, the entire coiled-up sheet may have stretchable elements formed therein, the stretchable elements may define a longitudinal stretchable region extending between first

and second ends of the coiled-up sheet and/or the stretchable elements may define a stretchable crowning end on one end of the coiled-up sheet. In the latter embodiments, the coiled-up sheet generally includes a substantially nondeformable region which may have a substantially rigid lattice-like structure. The stent may also include a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions.

In accordance with another aspect of the present invention, a method is provided for making a coiled-sheet stent. A substantially flat sheet may be provided defining a length and a width. A plurality of stretchable elements may be formed in the sheet, the stretchable elements being expandable along the width of the sheet between an unstretched condition and a stretched condition. If desired, a plurality of locking elements may also be formed along an edge of the sheet extending along the length thereof. The stretchable elements and/or locking elements may be formed in the sheet, for example, by chemical etching, laser cutting or die punching. The flat sheet may be rolled about the width into a coiled-up sheet having overlapping inner and outer

longitudinal sections, thereby providing a coiled-sheet stent having stretchable elements formed therein.

In a preferred form, the sheet is formed from a shape memory material, and at least one of the unstretched and stretched shapes is programmed into the shape memory material during the step of forming the stretchable elements. For example, the stretchable elements may be formed in the sheet in the stretched shape, and the sheet may be heat treated to program the stretched shape into the shape memory material. The stretchable elements may then be constrained in the unstretched shape after the heat treating step, for example, upon cooling the sheet after the heat treating step, and may be plastically deformed to their unstretched shape after the cooling step.

More preferably, the flat sheet is formed from Nitinol. During the heating step, the Nitinol may include austenite, and preferably the sheet is heated to a temperature of at least about body temperature, the temperature being sufficiently high such that the Nitinol substantially completes austenitic transformation. Upon cooling the sheet after the heat treating step, the Nitinol may include martensite, and preferably the sheet is cooled to a temperature of about 25 degrees Celsius or

less, the temperature being sufficiently low such that the Nitinol substantially completes martensitic transformation.

In an alternative method, the stretchable elements may be formed in the sheet in their unstretched shape, and then
5 plastically deformed to their stretched shape. The sheet may be heat treated to program the stretched shape into the shape memory material. After the heat treating step, the sheet may be cooled, thereby causing the stretchable elements to return to their unstretched shape.

The resulting coiled-sheet stent may then be used in a method for treating a patient, for example, at a target stenosis in a blood vessel, such as in the carotid or coronary arteries. A coiled-sheet stent is provided that preferably is formed from a temperature-activated shape memory material, the coiled-sheet
10 stent including a plurality of stretchable elements having a shape memory defining an unstretched condition and a stretched condition. The stretchable elements are preferably biased to assume the stretched condition when exposed to a temperature at or above body temperature.

20 The coiled-sheet stent may be provided in a contracted condition on a delivery device, for example, within a distal end of a tubular sheath, at a temperature substantially below body

temperature. For example, the coiled-sheet stent may be placed on a catheter which may be introduced into a lumen within the sheath, or the coiled-sheet stent may be placed within the distal end of the sheath adjacent a slidable bumper member.

5 The distal end of the sheath, with the stent therein, may be percutaneously introduced into a blood vessel or other body lumen of a patient, and advanced to a target treatment location. As the coiled-sheet stent becomes exposed to the body temperature within the patient during advancement, the stretchable elements become biased to assume the stretched shape due to the stent's shape memory. The stent may then be deployed, for example, by retracting the sheath while maintaining the stent at the target treatment location, the coiled-sheet stent at least partially expanding towards an enlarged condition due to the bias of the stretchable elements towards the stretched shape.

10 If necessary or desired, the stent may be further expanded to an enlarged condition at which the coiled-sheet substantially engages the vessel wall at the target treatment location, for example, by introducing a balloon within the deployed stent.

20 When the balloon is deflated and withdrawn, the stent may attempt to return to its contracted condition. However, the stent preferably includes locking elements which substantially engage

openings in the stent to substantially lock the stent in its enlarged condition.

5 The stretchable elements formed in the sheet of the coiled-sheet stent may be useful to allow recoil of the stent after implantation in a blood vessel. For example, after implantation of the stent, the blood vessel may tend to contract, thereby subjecting the stent to radially compressive forces. The stretchable elements may elastically or plastically deform from the stretched shape towards the unstretched shape to substantially reduce the risk that the stent may buckle under the compressive forces, thereby allowing the stent to partially recoil under the compressive forces.

15 The stretchable elements may also contribute to the initial expansion of the coiled-sheet stent upon deployment, thereby facilitating withdrawal of the delivery device, such as an underlying catheter. The combination of the bias of the stretchable elements and a bias of the coiled-sheet itself to at least partially unwind may eliminate the need for subsequent further expansion of the coiled-sheet stent, as will be appreciated by those skilled in the art.

Other objects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

5 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a side view of an unrolled coiled-sheet for a fully stretchable coiled-sheet stent, in accordance with one aspect of the present invention.

FIG. 1B is an end view of the coiled-sheet of FIG. 1A rolled into a coiled-sheet stent.

FIG. 2A is an end view of a coiled-sheet stent with a longitudinal anti-buckling region.

FIG. 2B is a top view of an unrolled coiled-sheet corresponding to the stent of FIG. 2A.

FIG. 3A is a top view of an unrolled coiled-sheet corresponding to a coiled-sheet stent having a stretchable end region.

FIG. 3B is a perspective view of the coiled-sheet of FIG. 3A being rolled into a coiled-sheet stent with stretchable end region.

FIGS. 4A and 4B are top views of an unrolled stretchable segment of a coiled-sheet stent, showing a first preferred

embodiment of a stretchable cell structure in unstretched and stretched conditions, respectively.

FIGS. 5A and 5B are details of the stretchable cell structure of FIGS. 4A and 4B, shown in unstretched and stretched conditions, respectively.

FIGS. 6A and 6B show a second preferred embodiment of an unrolled stretchable segment made of inverting elements, shown in unstretched and stretched conditions, respectively.

FIGS. 7A and 7B show a third preferred embodiment of an unrolled stretchable segment made of trapezoidal elements, shown in unstretched and stretched conditions, respectively.

FIG. 8A shows a fourth preferred embodiment of an unrolled stretchable segment, shown in its unstretched condition.

FIG. 8B is a detail of an individual stretchable element of the stretchable segment of FIG. 8A, in its stretched condition.

FIG. 9 shows a fifth preferred embodiment of an unrolled stretchable segment, shown in its unstretched condition.

FIGS. 10A and 10B are details of the stretchable segment of FIG. 9, shown in unstretched and stretched conditions, respectively.

FIG. 11 shows a sixth preferred embodiment of a unrolled stretchable segment in its unstretched condition.

FIG. 12 shows a seventh preferred embodiment of an unrolled coiled-sheet having stretchable elements.

FIG. 13 is a top view of an unrolled coiled-sheet having a flared crowning end on one end of a uniform segment.

FIG. 14 shows alternate preferred embodiments of an unrolled stretchable segment formed from interwoven sinusoidal segments.

FIGS. 15A and 15B show details of a conventional stent strut structure, in perspective and cross-sectional views, respectively.

FIGS. 16A and 16B show details of an inverted stent strut structure in accordance with the present invention, in perspective and cross-sectional views, respectively.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings, FIGS. 1A and 1B show a first preferred embodiment of a coiled-sheet stent 10, in accordance with one aspect of the present invention. The coiled-sheet stent 10 is formed from a substantially flat sheet 12 having first and second ends 14, 16 defining a longitudinal axis 18 therebetween. The sheet 12 also includes first and second longitudinal edges 20, 22, the first edge 20 having a plurality of fingers or teeth

24 extending therefrom substantially perpendicular to the longitudinal axis 18.

The sheet 12 also includes a plurality of stretchable elements 30 formed therein, thereby defining a multi-cellular structure capable of expanding and/or contracting in a direction substantially perpendicular to the longitudinal axis 18.

Preferably, the stretchable elements 30 define a lattice-like structure providing a plurality of openings 32 for receiving the teeth 24, as described further below. The stretchable elements 30 may be elastically deformable, i.e., biased to assume a first shape but temporarily deformable from that first shape, and/or may be plastically deformable, i.e., assuming any shape to which the stretchable elements 30 are deformed.

As best seen in FIG. 1B, the sheet 12 is preferably provided in a coiled-up condition, defining overlapping inner and outer longitudinal sections 26, 28 that may slide with respect to one another to allow radial expansion of the coiled-sheet 12 between a contracted condition and one or more enlarged conditions. The coiled-up sheet 12 may be biased to the contracted condition, thereby requiring a balloon or other expandable member to radially expand the stent 10 to the enlarged condition, and/or

the coiled-sheet 12 may be biased to at least partially radially expand.

In a preferred form, the stretchable elements 30 have a temperature-activated shape memory. For example, at a first temperature, the stretchable elements 30 may be biased to assume a peripherally contracted or "unstretched" shape, while at a higher second temperature, the stretchable elements 30 may become biased to assume a peripherally expanded or "stretched" shape. Preferably, the first temperature is generally about ambient temperature, such as about 25 degrees Celsius or less, and the second temperature is generally about body temperature, such as about 37 degrees Celsius or higher.

To manufacture a coiled-sheet stent 10 as described, a relatively thin, substantially flat sheet 12 is provided, for example, having a thickness of about 2-4 mm, formed from a biocompatible material, such as stainless steel or a polymer. More preferably, the sheet 12 is formed from a shape memory polymer or metal, such as a nickel-titanium alloy ("Nitinol"), more preferably having a thermally-activated shape memory. Alternatively, an elastic material, such as tantalum, platinum or tungsten alloy, or a super-elastic material, such as Nitinol, may be used. The stretchable elements 30, the teeth 24 and/or any

other openings in the sheet 12 may be formed using a number of conventional metal working processes, such as die and punch, laser cutting, or chemical etching.

In one preferred method, the stretchable elements 30 are formed in their stretched shape and the sheet 12 is subsequently heat treated, for example, to a temperature of about 500 degrees Celsius or more, for a predetermined time to activate the shape memory of the material, as is known in the art. After the sheet 12 has cooled, the stretchable elements 30 are compressed into their unstretched shape, and the sheet 12 is rolled to provide a coiled-sheet stent 10.

Preferably, the sheet is formed from Nitinol which, when heat treated, is converted substantially to its austenitic phase, i.e., set to assume its stretched shape. As it is cooled, the Nitinol material preferably undergoes martensitic transformation. When the stretchable elements 30 are compressed into their unstretched shape, the material is plastically deformed substantially as martensite. More preferably, a Nitinol alloy is selected such that transformation back to austenite occurs by the time the material reaches body temperature, e.g., about 37 degrees Celsius. Thus, the stretchable elements 30 may

automatically become biased to assume the stretched shape upon reaching body temperature, as explained further below.

In another preferred method, the stretchable elements 30 may be formed in their unstretched shape, and then plastically deformed to their stretched shape, e.g., while the Nitinol material is in its martensitic phase. The sheet 12 may then be heat treated, e.g., to transform the material to its austenitic phase, thereby storing the stretched shape in the material's shape memory. Upon cooling, the material will transform back to martensite, thereby returning to the unstretched shape. The sheet 12 may then be rolled into its contracted condition for placement on a delivery device (not shown).

For example, the coiled-sheet stent 10, in its contracted condition, may be placed over the distal end of a delivery catheter (not shown) having a size adapted for percutaneous introduction into a patient's vasculature. A retractable sheath (not shown) may be advanced over the distal end, thereby protecting the stent 10, preventing shifting and/or preventing premature deployment. The distal end of the catheter-sheath assembly may then be percutaneously introduced into a patient's vasculature, and advanced to a target treatment location, such as a stenosis within the carotid or coronary arteries.

As the stent 10 reaches body temperature, the temperature-activated shape memory of the material is preferably activated such that the stretchable elements 30 become biased to assume their stretched shape, e.g., when the Nitinol completes transformation back to austenite. Thus, the sheath constrains the stent 10 from at least partially expanding because of the stretching of the stretchable elements 30. Once the stent 10 is properly positioned at the treatment location, the sheath may be retracted, thereby exposing the stent 10, which may then at least partially expand radially as the stretchable elements 30 assume their stretched shape.

The catheter-sheath assembly may be withdrawn, and a balloon catheter (not shown) may be introduced into the interior of the partially expanded stent 10. Alternatively, a balloon or other expandable member (not shown) may be provided on the delivery catheter adjacent to the stent 10. The balloon may be inflated, thereby further radially expanding the stent 10. Once a desired enlarged condition is achieved, the balloon is deflated and withdrawn. Preferably, the teeth 24 on the inner longitudinal edge 20 engage a set of the openings 32 in the sheet 12, thereby substantially locking the stent 10 in its enlarged condition. Thus, the teeth 24 allow the stent 10 to be ratcheted to a number

of enlarged conditions as long as the inner and outer longitudinal sections 26, 28 overlap and allow the teeth 24 to engage corresponding openings 32, as will be appreciated by those skilled in the art.

5 Turning to FIGS. 2A and 2B, a second preferred embodiment of a coiled-sheet stent 110 is shown that includes a longitudinal stretchable anti-buckling region 134. The stent 110 is formed from a sheet 112 including a plurality of stretchable elements 130, similar to the previous embodiment, that are arranged
10 substantially parallel to the longitudinal axis 118, thereby defining the longitudinal stretchable region 134.

15 In addition, however, the sheet 112 includes substantially nonstretchable regions 136, 138, which preferably define a lattice-like structure formed from substantially nondeformable elements 140. For example, the thickness of the elements forming the lattice in the nonstretchable regions 136, 138 may be substantially thicker than the stretchable elements 130 in the stretchable region 134. Alternatively, the shape of the stretchable elements 130 may facilitate expansion and/or
20 contraction perpendicular to the longitudinal axis 118. For example, in a preferred form, the lattice of the nonstretchable regions 136, 138 may be substantially rectangular, and more

preferably square, to provide enhanced rigidity both parallel and perpendicular to the longitudinal axis 118.

As best seen in FIG. 2A, the sheet 12 may be rolled into the coiled-sheet stent 110, thereby providing overlapping inner and outer longitudinal sections 126, 128 such that the stretchable region 134 extends axially, i.e., substantially parallel to the longitudinal axis 118. Similar to the previous embodiment, the sheet 112 may be formed from a shape memory material, such as Nitinol, which may be stretched and heat treated, and then cooled and unstretched, or otherwise have a shape memory programmed into the material.

The longitudinal-oriented stretchable region 134 may facilitate the stent 110 partially recoiling when subjected to radially compressive forces. Once the stent 110 has been expanded and locked in an enlarged condition, the nondeformable elements 140 remain substantially rigid and will not recoil. The stretchable elements 130, however, may be compressed about the diameter of the stent 110, i.e., may be elastically or plastically deformed towards their unstretched shape when the stent 110 is subjected to radially compressive forces. Thus, the stent 110 may combine the benefits of both a coiled-sheet stent,

which is generally incompressible about its diameter, and a stretchable stent structure.

Turning to FIGS. 3A and 3B, a third preferred embodiment of a coiled-sheet stent 210 is shown that is formed from a sheet 212 including a stretchable region or "crowning end" 234 extending from one end 215 of a nondeformable region 236. Both regions 234, 236 may include teeth 224a, 224b extending from a longitudinal side edge 220 thereof, and may be rolled to define a longitudinal axis 218. The sheet 212 preferably has a shape memory, e.g., may be polished, heat treated into its stretched shape, cooled and unstretched, and then is preferably rolled into its contracted condition. When the shape memory is programmed into the sheet material, the stretchable region 234 may be shaped to assume a radially outwardly flared shape (not shown) that may facilitate anchoring of the end of the stent 210.

After the stent 210 has been implanted, the stent 210 may be subjected to radially compressive forces due to the elasticity of the vessel wall, which may cause the stretchable elements 230 in the stretchable region 234 to become compressed, similar to the embodiments described above, thereby allowing the ends of the stent 210 to partially recoil while still substantially anchoring the stent 210 in position. Alternatively, the end 216 of the

stretchable region 234 may be flared outward to thereby partially recoil under radially compressive forces such that the stent adopts a substantially uniform size upon implantation within a blood vessel.

5 In alternative configurations, the coiled-sheet stents described herein may also include outwardly-oriented hooks or barbs (not shown) for enhancing anchoring of the stent within a body passage. Pro-thrombotic material (not shown) may be provided on the exterior surfaces of the coiled-sheet stent to enhance sealing against the wall of the body passage. Additional information on coiled-sheet stents may be found, for example, in U.S. Patent Nos. 4,577,631 issued March 25, 1986 in the name of Kreamer, 5,007,926 issued April 16, 1991 in the name of Derbyshire, 5,158,548 issued October 28, 1992 in the name of Lau et al., Re 34,327 reissued July 27, 1993 in the name of Kreamer, 5,423,885 issued June 13, 1995 in the name of Williams, 5,441,515 issued August 15, 1995 in the name of Khosravi et al., and 5,443,500 issued August 22, 1995 in the name of Sigwart. The disclosures of these references and any others cited therein are
20 expressly incorporated herein by reference.

The stretchable elements included in the coiled-sheet stents described herein may take on a number of different forms.

Generally, a plurality of stretchable elements are provided in a predetermined arrangement, such as the longitudinal or radial configurations described above, although a variety of arrangements providing a desired recoil or flexibility

5 characteristic may be provided. Thus, each stretchable element generally comprises an individual cell, thereby providing a multi-cellular structure when the individual cells are duplicated in a predetermined pattern, as in the preferred embodiments described below. In describing these several preferred
10 embodiments for the stretchable elements, a suffix "a" after reference numbers is used to refer to the unstretched shape, a suffix "b" is used to refer to the stretched shape, and no suffix is used when simply describing elements generally. Further, the terms "longitudinal" and "longitudinally" refer to those elements
15 in each individual cell oriented towards the ends of the stent, i.e., arranged generally along the longitudinal axis, while the terms "peripheral" and "peripherally" refer to those elements oriented about the diameter of the stent, i.e., arranged generally perpendicular to the longitudinal axis.

20 Returning to the drawings, FIGS. 4A, 4B, 5A and 5B show a first preferred embodiment of a plurality of stretchable elements 330 defining a multi-cellular stretchable region 332 which may be

incorporated into a coiled-sheet stent, such as those described above. Each stretchable element 330 has a generally diamond shape defined by four substantially straight segments 334 defining longitudinal apices 336 and peripheral apices 338. The
5 straight segments 334 are generally arranged such that each stretchable element 330 has a longer longitudinal dimension or length 340 and a shorter peripheral dimension or width 342.

Preferably, the peripheral ends of the straight segments 334 include peripherally extending regions 344, defining a nipple-shaped region 346 at which adjacent stretchable elements 330 are
10 connected. As best seen in FIGS. 5A and 5B, the nipple-shaped regions 346 may extend longitudinally as the stretchable elements 330 expand from their unstretched shape (FIG. 5A) to their stretched shape (FIG. 5B), thereby reducing axial foreshortening
15 of the stretchable region 332.

Because the width 342 of each stretchable element 330 is substantially smaller than the length 340, when the stretchable elements 330 expand from their unstretched shape to their stretched shape, a substantial increase in the peripheral
20 dimension may be achieved with minimized longitudinal foreshortening. For example, in the embodiment shown, about three hundred percent peripheral expansion may be achieved with

only about twelve percent foreshortening. Minimizing
foreshortening may be desirable to minimize the risk of shearing
along a vessel wall, which may dislodge plaque, and/or to ensure
that the stent does not migrate or otherwise shift with respect
5 to a target treatment location.

Turning to FIGS. 6A and 6B, a second preferred embodiment of
a plurality of stretchable elements 430 defining a stretchable
region 432 is shown. Similar to the previous embodiment, each
stretchable element 430b has a generally diamond shape in its
stretched shape (FIG. 6A), although, unlike the previous
embodiment, each stretchable element 430a has a generally
triangular or arrowhead shape in its unstretched shape (FIG. 6B).
This is due to each stretchable element 430 having doubled or
thicker substantially straight segments 434 on one side of the
stretchable element 430 and single substantially straight
15 segments 435 on the other side.

The shape memory is programmed into the material such that
the single straight segments 435 "invert," i.e., change their
orientation from being oriented generally towards the opposing
20 double straight elements 434 in the unstretched shape to being
oriented generally away from the opposing double straight
elements 434 in the stretched shape. The inversion of the single

straight elements 435 allows the stretchable elements 430 to expand peripherally with substantially no longitudinal foreshortening or growth. Stated differently, the width 442 of the stretchable elements 430 may increase substantially, while the length 440 of the stretchable elements 430 remains substantially constant before and after expansion.

Turning to FIGS. 7A and 7B, a third preferred embodiment of a plurality of stretchable elements 530 is shown that define a stretchable region 532. The stretchable elements 530 define a generally parallelogram shape. Opposing straight segments 534 in each stretchable element 530 remain generally parallel to one another as the stretchable elements 530 are expanded from their unstretched shape (FIG. 7A) to the stretched shape (FIG. 7B). The parallelogram shape may be desirable because of its simplicity to form. If the unstretched and stretched shapes are properly selected, i.e., the length and width of the parallelogram shapes are provided in a predetermined ratio, the stretchable elements 530 may experience substantial growth in width 542 with minimal net change in length 540.

Turning to FIGS. 8A and 8B, a fourth preferred form of a stretchable region 632 is shown that is defined by a plurality of stretchable elements 630. A plurality of generally zigzag or

sinusoidal segments 636 extend generally perpendicular to the longitudinal axis 618, and a plurality of longitudinal segments 634 extend generally parallel to a longitudinal axis 618 to connect the zigzag segments 636. The longitudinal segments 634 are preferably located at the peaks and valleys of the zigzag elements 636. Thus, each stretchable element 630 is symmetrical and is defined by opposing portions of longitudinal segments 634 and opposing portions of zigzag segments 636 with a portion of a longitudinal segment 634 extending axially therethrough at an intermediate location.

Preferably, in their unstretched shape, as shown in FIG. 8A, the zigzag segments 636a have a curved or bent configuration that minimizes the peripheral dimension or width 642a of the stretchable elements 630a. In their stretched shape, as shown in FIG. 8B, the zigzag segments 636b may substantially straighten and/or assume a more peripherally-oriented configuration, thereby substantially increasing the width 642b of the stretchable elements 630b. Thus, a desired peripheral expansion may be stored in the zigzag segments 636, while a minimal longitudinal foreshortening is encountered during expansion because of the fixed longitudinal segments 634. The change in the overall longitudinal dimension or length of the stretchable region 632

during expansion is constant no matter the length of the stretchable region, which may be desirable for relatively long stents. It occurs from the relative axial movement of adjacent longitudinal segments 634 as the stretchable elements 630 are expanded peripherally.

Turning to FIGS. 9, 10A and 10B, a fifth preferred embodiment of a plurality of stretchable segments 730 defining a stretchable region 732 is shown. The stretchable segments 730 are arranged in peripherally-oriented cells 734, wherein adjacent stretchable segments 730 are connected by peripheral connector elements 736. In their unstretched shape, each stretchable element 730a is made up of a pair of longitudinal-oriented "wings" 738a. Each wing 738a includes first and second longitudinal elements 740, 742 that extend longitudinally from adjacent peripheral connector elements 736 to a looped end 744. The longitudinal elements 740, 742 preferably extend generally parallel to one another, for example, in an undulated pattern along the longitudinal axis, although alternatively, the longitudinal elements 740, 742 may be substantially straight. Stretchable elements 730 adjacent to one another in adjacent cells along the longitudinal axis 718 are preferably connected by their looped ends 744, as shown.

As shown in FIG. 10B, when the stretchable elements 730b are expanded to their stretched shape, the wings 738b open peripherally, i.e., the adjacent peripheral connectors 736 and the longitudinal elements 740, 742 are directed peripherally away from one another. Because of the undulated pattern in the longitudinal elements 740, 742, longitudinal foreshortening of the stretchable elements 730 may be minimized by at least partial straightening of the longitudinal elements 740b, 742b.

Turning to FIG. 11, a sixth preferred embodiment of a stretchable region 832 is shown that is defined by a plurality of stretchable elements 830 that are connected together in a predetermined pattern. Each stretchable element 830 is formed from a generally octagonal-shaped segment 834 having a pair of substantially straight cross segments 836 extending across from opposite corners. Connector elements 838, 840 connect adjacent octagonal-shaped segments 834 at the corners not connected by the crossing segments 836.

Turning to FIG. 12, a seventh preferred embodiment of a plurality of stretchable elements 930 formed into flat sheet 932 is shown. Each stretchable element 930 has a generally honeycomb shape, thereby defining openings 926 for receiving corresponding teeth 924 therein. The stretchable elements 930 are arranged in

peripherally-oriented cells 934, with adjacent cells 934 being connected together by generally "O" shaped segments. The honeycomb structure of the stretchable elements 930 may facilitate the stretchable region 932 partially recoiling when
5 subjected to radial forces, as will be appreciated by those skilled in the art.

Turning to FIG. 13, another preferred embodiment of a flat sheet 1012 for a coiled-sheet stent is shown that includes a substantially nondeformable section 1036 and a stretchable section 1034. The nondeformable section 1036 is formed from a plurality of diamond-shaped elements 1030 defining openings 1032 for receiving teeth 1024 therein. The stretchable section 1034 provides a flared crowning end on the flat sheet 1012, which is formed from a plurality of diamond-shaped elements 1038. The
15 diamond-shaped elements 1038 in the stretchable section 1034 are substantially larger and less dense than the elements 1030 in the nondeformable section 1036, thereby providing less resistance to peripheral deformation and facilitating partial recoiling of the stretchable section 1034.

20 Turning to FIG. 14A, another preferred embodiment of a stretchable region 1132 is shown that is formed from a plurality of interwoven sinusoidal elements 1134. The sinusoidal elements

1134 are arranged generally parallel to the longitudinal axis
1118 and are spaced apart along the longitudinal axis from one
another, thereby providing a generally diamond-shaped lattice
structure. The lattice structure may facilitate partial recoil
5 of the stretchable region 1132 when a coiled-sheet stent (not
shown) formed therefrom is subjected to radial compressive
forces, as previously described.

In accordance with another aspect of the present invention,
a generally tubular stent is provided that includes an inverted
strut structure. Generally, tubular stents have a set of struts
or beams formed therein which provide the structural support for
the stent. The configuration of the struts, e.g., multi-
cellular, helical, etc., and the construction of the stent itself
may provide a variety of different features. For example, a
coiled-sheet stent may be desirable because of the ability to
precisely control the expansion of the stent to ensure secure
engagement with a vessel lumen. Plastically deformable and
elastically expandable tubular stent structures are also
available, which have their own advantages and disadvantages.

20 Generally, stents are formed from a flat or tubular sheet
into which the strut structure is formed by a variety of known
methods, although alternatively round or flat wires may be used

to form the stent. The resulting stent is a generally tubular body expandable between a contracted condition for facilitating introduction into a body lumen, and an enlarged condition for engaging the body lumen. The tubular body has open ends defining a longitudinal axis therebetween. Struts formed in the tubular body have a width dimension extending along a periphery of the tubular body, and a thickness dimension extending radially outward substantially perpendicular to the longitudinal axis.

For reference, FIGS. 15A and 15B show a detail of a segment of a conventional stent strut structure 1210 that includes a pair of struts 1212a, b. For conventional stents, the thickness dimension "t" of individual struts 1212 is generally substantially smaller than the width dimension "w." This ratio may be considered important, for example, to minimize profile of the resulting stent to facilitate delivery and/or to minimize the protrusion of the stent, after implantation, into the lumen of the vessel, which may obstruct flow or become a source for thrombosis development.

Turning to FIGS. 16A and 16B, a detail of a segment of stent strut structure 1310 in accordance with the present invention is shown. The strut structure 1310 includes a plurality of struts 1312a, extending peripherally and/or longitudinally along all or

1 a portion of the stent (not shown). The resulting stent may have
2 a number of possible configurations, such as the coiled-sheet
3 stents described above. Alternatively, tubular plastically
4 deformable stents or stents elastically biased to expand may be
5 provided with the features of the present invention, as will be
6 appreciated by those skilled in the art.

7 The struts 1312 have a thickness dimension "t" that extends
8 radially outward substantially perpendicular to a longitudinal
9 axis of the stent (not shown), and a width dimension "w" that
10 extends peripherally and/or longitudinally along the stent wall.
11 As may be seen, the thickness dimension "t" is substantially
12 greater than the width dimension "w." Stated differently, the
13 ratio of width to thickness dimensions is less than one.

14 The "inverted" strut structure, i.e., a strut structure
15 having a greater thickness dimension "t" than width dimension
16 "w", has several advantages. For example, because the width
17 dimension "w" is smaller than the thickness dimension "t," the
18 strut structure may be more easily deformed along the periphery
19 in order to facilitate substantially even expansion of the
20 resulting stent. This is illustrated by reviewing the moment of
21 inertia "I" of the strut 1312a about flexural axis A-A, which for
22 a rectangular cross-section is defined as:

$$I_{A-A} = 1/12 w^3 t. \quad (1)$$

The moment of inertia "I_{A-A}" about this axis is predominated by the narrower dimension "w." The moment of inertia about the axis A-A is important because the deflection of the struts 1212 in a plane defined by the axis A-A is generally the mechanism that allows the stent to expand radially outward, as the struts deflect peripherally away from one another. Thus, the struts 1212 may provide increased flexibility as compared to conventional stent struts, which have a larger width dimension "w" than thickness dimension "t."

In contrast, the moment of inertia "I" of the strut 1312a about flexural axis B-B may be substantially higher, as given by the following equation:

$$I_{B-B} = 1/12 t^3 w. \quad (2)$$

Because the moment of inertia "I_{B-B}" is predominated by the thickness dimension "t," the struts 1312 may be substantially more resistant to radial bending. Stated differently, because the moment of inertia "I_{B-B}" is relatively higher than

conventional stent struts having the thickness dimension "t" substantially smaller than the width dimension "w," the struts 1312 minimize the likelihood of out-of-plane bending which will also ensure more even expansion of the stent within a body lumen.

5 The increased resistance to radial deflection may also reduce recoil and/or the risk of the stent buckling under compressive forces imposed by the vessel wall after implantation.

Because of the increased thickness "t" of the struts 1312, the resulting profile of the stent, after implantation, may not be appropriate for smaller vessels, such as the coronary arteries or cerebrovascular sites. More preferably, the inverted strut structure 1310 may be used for applications within the carotid, iliac, renal and/or femoral arteries.

10 15 20 While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

WHAT IS CLAIMED IS:

1. A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, the coiled-up sheet being expandable between a contracted condition and one or more enlarged conditions; and

a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements being expandable between an unstretched condition and a stretched condition.

2. The stretchable stent of claim 1, wherein the coiled-up sheet is at least partially biased to expand from the contracted condition towards the one or more enlarged conditions.

3. The stretchable stent of claim 1, wherein the stretchable elements are biased to assume the stretched condition, thereby at least partially biasing the coiled-up sheet to radially expand from the contracted condition towards the one or more enlarged conditions.

4. The stretchable stent of claim 1, wherein the coiled-up sheet defines a periphery substantially perpendicular to the longitudinal axis, and wherein the stretchable elements are expandable about the periphery of the coiled-up sheet.

5

5. The stretchable stent of claim 1, wherein the coiled-up sheet comprises a material having a temperature-based shape memory, whereby the stretchable elements are biased towards the unstretched condition when exposed to a first temperature and towards the stretched condition when exposed to a second temperature.

6. The stretchable stent of claim 5, wherein the second temperature is at or above body temperature.

7. The stretchable stent of claim 5, wherein the first temperature is at or below about 25 degrees Celsius.

8. The stretchable stent of claim 5, wherein the coiled-up sheet comprises Nitinol.

9. The stretchable stent of claim 8, wherein the Nitinol is substantially in its martensitic phase at the first temperature and substantially in its austenitic phase at the second temperature.

5

10. The stretchable stent of claim 1, wherein the entire coiled-up sheet has stretchable elements formed therein.

11. The stretchable stent of claim 1, wherein the stretchable elements define a longitudinal stretchable region extending between first and second ends of the coiled-up sheet.

12. The stretchable stent of claim 1, wherein the stretchable elements define a stretchable crowning end on one end of the coiled-up sheet.

13. The stretchable stent of claim 1, wherein the coiled-up sheet further comprises a substantially nondeformable region.

14. The stretchable stent of claim 13, wherein the nondeformable region comprises a substantially rigid lattice-like structure.

15. The stretchable stent of claim 1, further comprising a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer

5 longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions.

16. A stretchable stent, comprising:

50 a coiled-up sheet having overlapping inner and outer longitudinal sections, the coiled-up sheet being expandable between a contracted condition and one or more enlarged conditions, the coiled-up sheet defining a periphery in a plane substantially perpendicular to a longitudinal axis thereof;

55 a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions; and

60 a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements having a shape memory defining an unstretched condition and a stretched condition.

17. The stretchable stent of claim 16, wherein the stretchable elements are biased to assume the stretched condition when exposed to a temperature at or above body temperature.

5 18. The stretchable stent of claim 16, wherein the stretchable elements define a longitudinal stretchable region extending between first and second ends of the coiled-up sheet.

10 19. The stretchable stent of claim 16, wherein the stretchable elements define a stretchable crowning end on an end of the coiled-up sheet.

15 20. The stretchable stent of claim 16, wherein the coiled-up sheet comprises Nitinol.

21. The stretchable stent of claim 20, wherein the stretchable elements comprise austenite at or above body temperature.

20 22. The stretchable stent of claim 20, wherein the stretchable elements comprise martensite at or below about 25 degrees Celsius.

23. The stretchable stent of claim 1, wherein the coiled-up sheet comprises a nondeformable region that is generally incompressible about the periphery.

5

24. The stretchable stent of claim 23, wherein the nondeformable region comprises a lattice-like structure including the openings for receiving the locking elements.

25. The stretchable stent of claim 16, wherein the stretchable elements comprise a multi-cellular structure of diamond-shaped elements capable of assuming unstretched and stretched conditions.

26. The stretchable stent of claim 25, wherein the diamond-shaped elements comprise peripheral apices extending generally along the peripheral dimension, the peripheral apices having peripherally extending nipples for reducing longitudinal foreshortening when the diamond-shaped elements are directed from the unstretched condition to the stretched condition.

27. The stretchable stent of claim 25, wherein the diamond-shaped elements are partially invertable to assume the unstretched condition.

5 28. The stretchable stent of claim 16, wherein the stretchable elements define a multi-cellular structure comprising a plurality of zigzag elements extending about the periphery of the coiled-up sheet, and a plurality of longitudinal elements intersecting the zigzag elements.

10 29. The stretchable stent of claim 16, wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis.

15 30. The stretchable stent of claim 29, wherein the stretchable elements define a multi-cellular structure with peripherally adjacent stretchable elements being connected at a point intermediate the pair of wing-like elements.

20 31. A method for making a coiled-sheet stent, the method comprising the steps of:

providing a substantially flat sheet defining a length and a width;

forming a plurality of stretchable elements in the sheet, the stretchable elements being expandable along the width of the sheet between an unstretched condition and a stretched condition;

5 and

rolling the flat sheet about the width into a coiled-up sheet having overlapping inner and outer longitudinal sections.

32. The method of claim 31, wherein the sheet comprises a shape memory material, and wherein at least one of the unstretched and stretched shapes is programmed into the shape memory material during the step of forming the stretchable elements.

33. The method of claim 32, wherein the step of forming the stretchable elements comprises the steps of:

forming the stretchable elements in the sheet in the stretched shape; and

heat treating the sheet to program the stretched shape into the shape memory material.

34. The method of claim 33, comprising the additional step of constraining the stretchable elements in the unstretched shape after the heat treating step.

5 35. The method of claim 33, wherein the shape memory material comprises Nitinol, and wherein the Nitinol comprises austenite during the heat treating step.

36. The method of claim 35, wherein the sheet is heated to a temperature of at least about body temperature, the temperature being sufficiently high such that the Nitinol substantially completes austenitic transformation.

37. The method of claim 35, comprising the additional step of cooling the sheet after the heat treating step, the Nitinol comprising martensite after the cooling step.

38. The method of claim 37, wherein the sheet is cooled to a temperature of about 25 degrees Celsius or less, the temperature being sufficiently low such that the Nitinol substantially completes martensitic transformation.

39. The method of claim 37, comprising the additional step of plastically deforming the stretchable elements to their unstretched shape after the cooling step.

5 40. The method of claim 32, wherein the step of forming the stretchable elements comprises the steps of:

forming the stretchable elements in the sheet in their unstretched shape;

10 plastically deforming the stretchable elements to their stretched shape; and

heat treating the sheet to program the stretched shape into the shape memory material.

15 41. The method of claim 40, comprising the additional step of cooling the sheet after the heat treating step, thereby causing the stretchable elements to return to their unstretched shape.

20 42. The method of claim 31, wherein the stretchable elements are formed in the sheet by chemical etching, laser cutting or punching.

43. The method of claim 31, comprising the additional step of forming a plurality of locking elements along an edge of the sheet extending along the length thereof.

5 44. A method for deploying a coiled-sheet stent at a target treatment location within a patient's body, the method comprising the steps of:

providing a coiled-sheet stent comprising a temperature-activated shape memory material, the coiled-sheet stent comprising a plurality of stretchable elements having a shape memory defining an unstretched condition and a stretched condition, the stretchable elements being biased to assume the stretched condition when exposed to a temperature at or above body temperature;

15 providing the coiled-sheet stent in a contracted condition within a distal end of a tubular sheath at a temperature substantially below body temperature;

percutaneously introducing the distal end of the sheath into a blood vessel of a patient;

20 advancing the distal end of the sheath to a target treatment location, the coiled-sheet stent becoming exposed to a temperature within the patient of at least about body temperature

during advancement, whereby the stretchable elements become biased to assume the stretched shape; and

deploying the coiled-sheet stent at the target treatment location, the coiled-sheet stent at least partially expanding
5 towards an enlarged condition due to the bias of the stretchable elements towards the stretched shape.

45. The method of claim 44, comprising the additional step of further expanding the coiled-sheet to an enlarged condition at
10 which the coiled-sheet substantially engages the vessel wall at the target treatment location.

46. A stent for implantation within a body lumen of a patient, comprising:

15 a generally tubular body expandable between a contracted condition for facilitating introduction into a body lumen, and an enlarged condition for engaging the body lumen, the tubular body having open ends defining a longitudinal axis therebetween; and

a set of struts formed in the tubular body, the struts
20 having a width dimension extending along a wall of the tubular body, and a thickness dimension extending radially outward substantially perpendicular to the longitudinal axis;

wherein the ratio of the thickness dimension to the width dimension is greater than one.

47. The stent of claim 46, wherein the tubular body
5 comprises a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof.

48. The stent of claim 46, wherein the tubular body
10 comprises a substantially enclosed tubular structure.

49. The stent of claim 48, wherein the tubular structure is biased to assume the enlarged condition.

50. The stent of claim 48, wherein the tubular structure is
15 plastically deformable from the contracted condition to the enlarged condition.

ABSTRACT

A stretchable coiled-sheet stent includes a coiled-up sheet having overlapping inner and outer longitudinal sections that is expandable between contracted and enlarged conditions, and a plurality of stretchable elements formed in the coiled-up sheet which are expandable between unstretched and stretched conditions. The coiled-up sheet is preferably formed from a temperature-based shape memory material, such as Nitinol, and at least one of the unstretched and stretched shapes is programmed into the shape memory. For example, the stretchable elements may be initially formed in the stretched shape, and the sheet heat treated to program the stretched shape into the shape memory. After cooling, the stretchable elements may be constrained in the unstretched shape for delivery. Alternatively, the stretchable elements may be formed in the unstretched shape and plastically deformed to their stretched shape, and the sheet may be heat treated to program the stretched shape into the shape memory. Upon cooling, the stretchable elements may return to their unstretched shape. The coiled-sheet stent is delivered in its contracted condition with the stretchable elements in the unstretched shape. The stent is introduced into a blood vessel and advanced to a target location, exposing the stent to the body

temperature and activating the shape memory to bias the stretchable elements towards the stretched shape. The stent is deployed, at least partially expanding towards the enlarged condition due to the bias of the stretchable elements towards the

5 stretched shape.

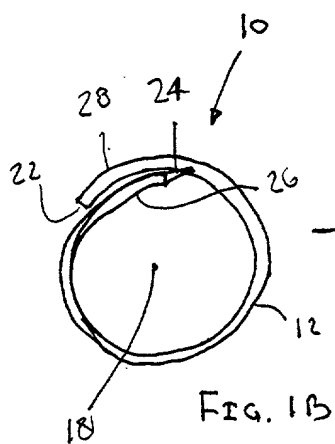


FIG. 1B

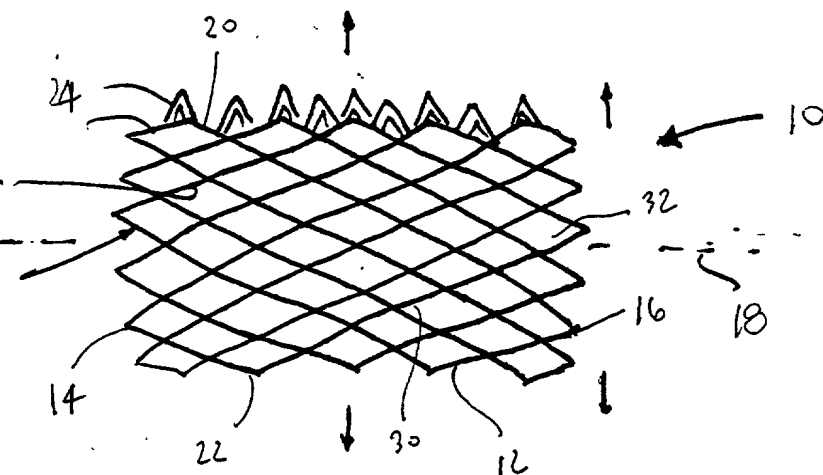


FIG. 1A

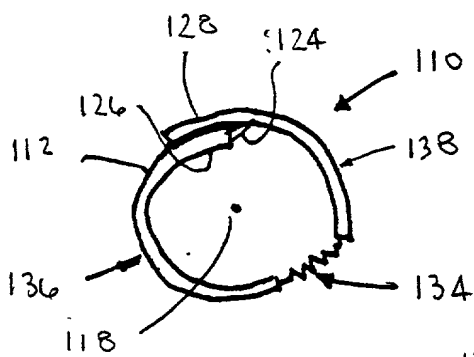


FIG. 2A

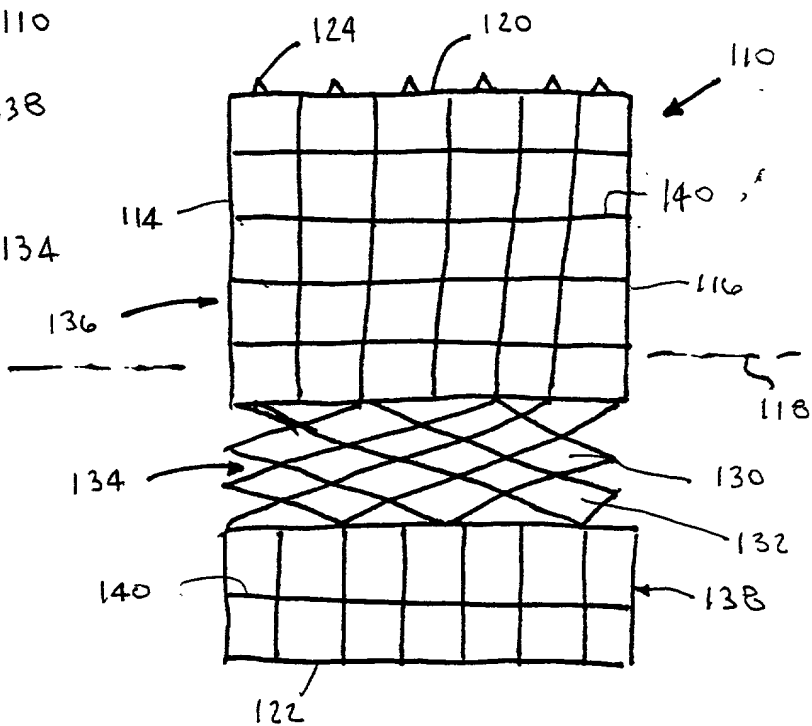
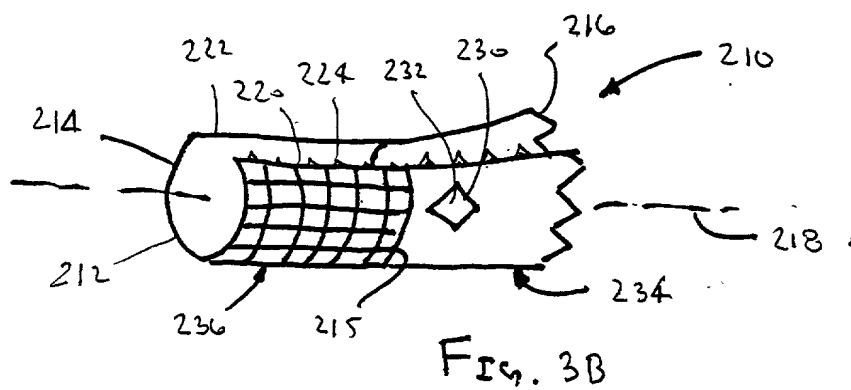
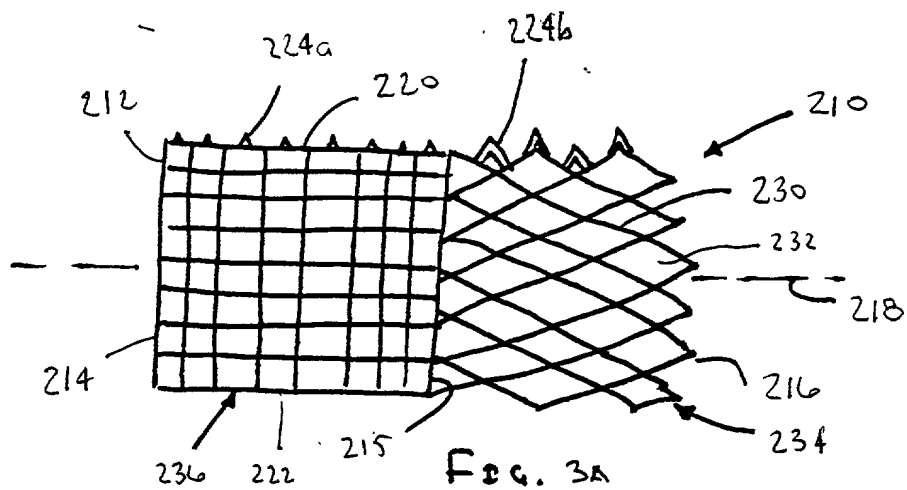
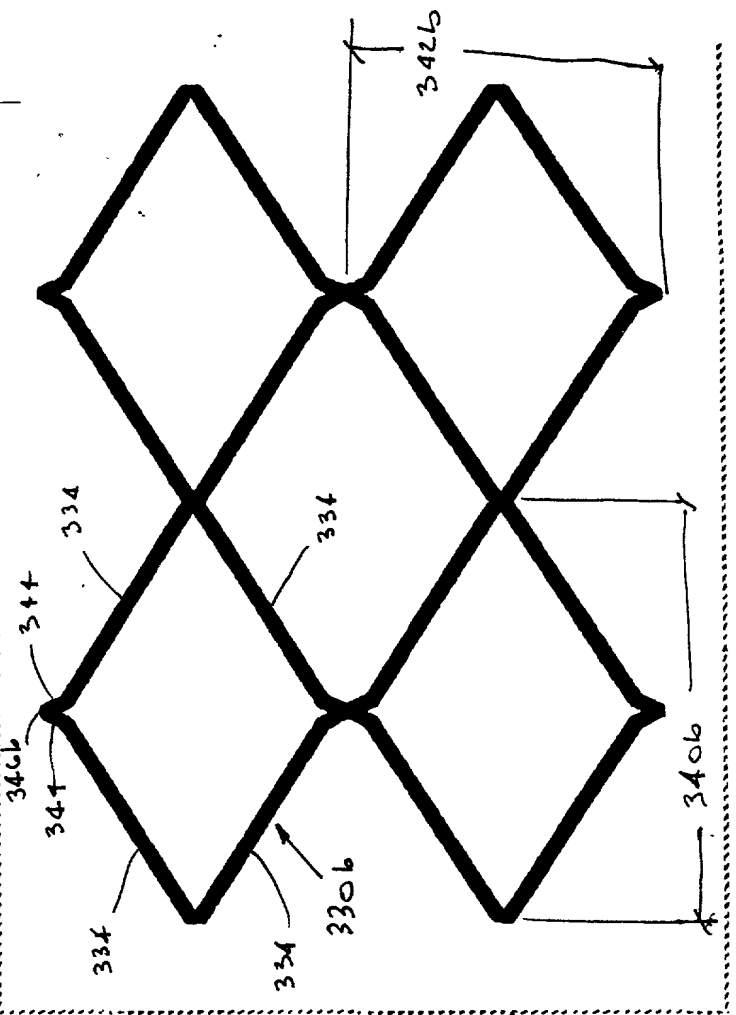
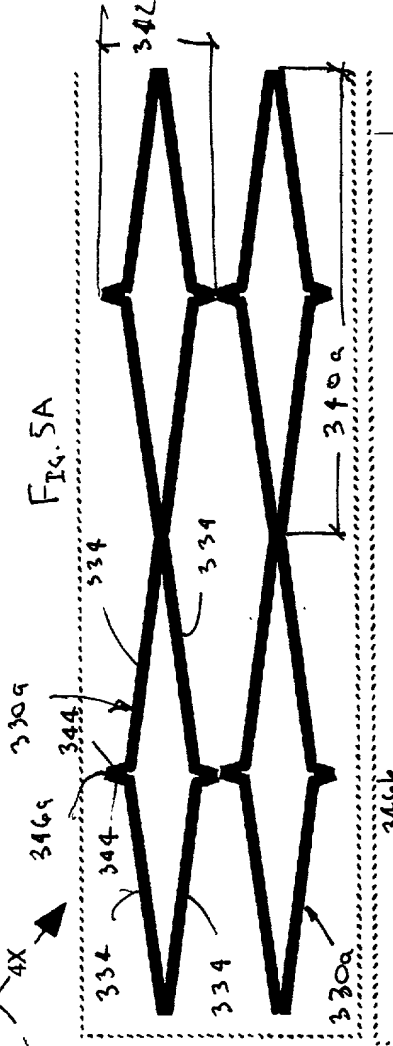
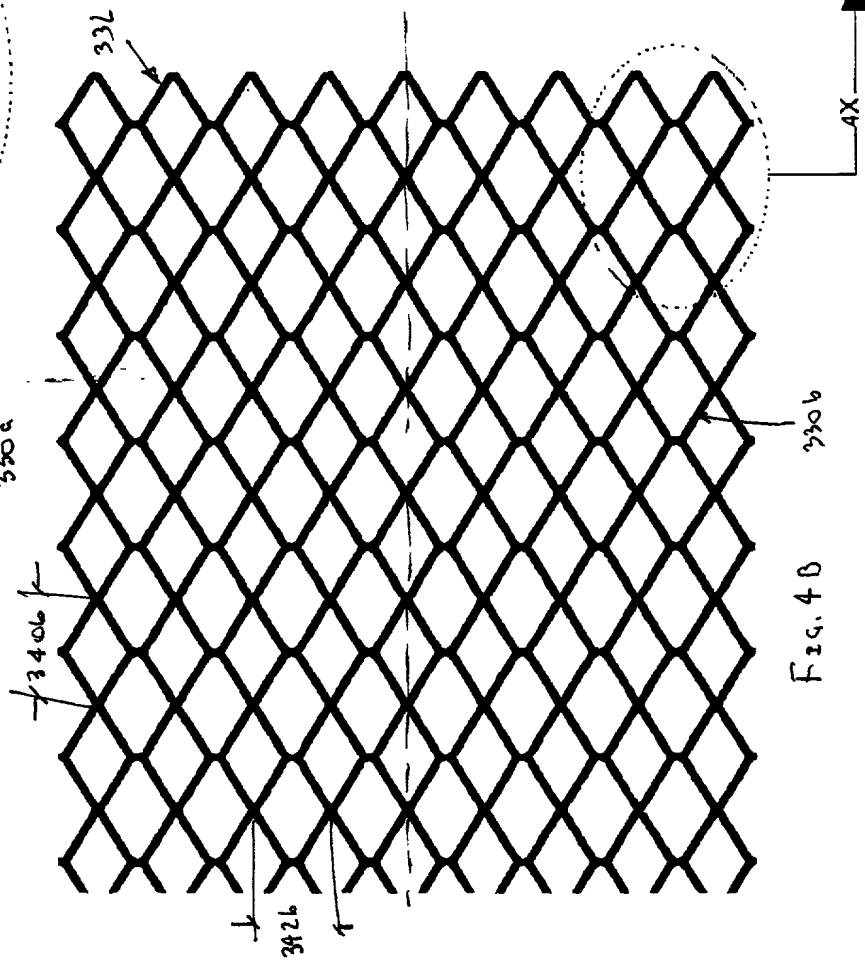
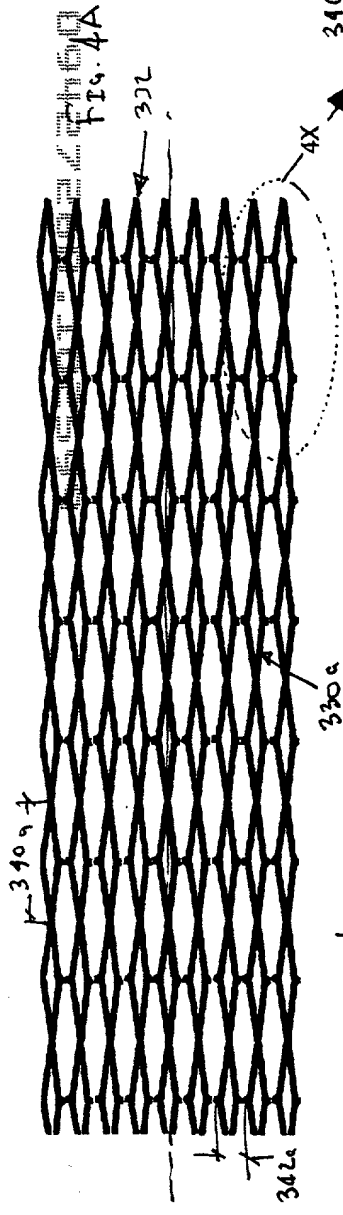
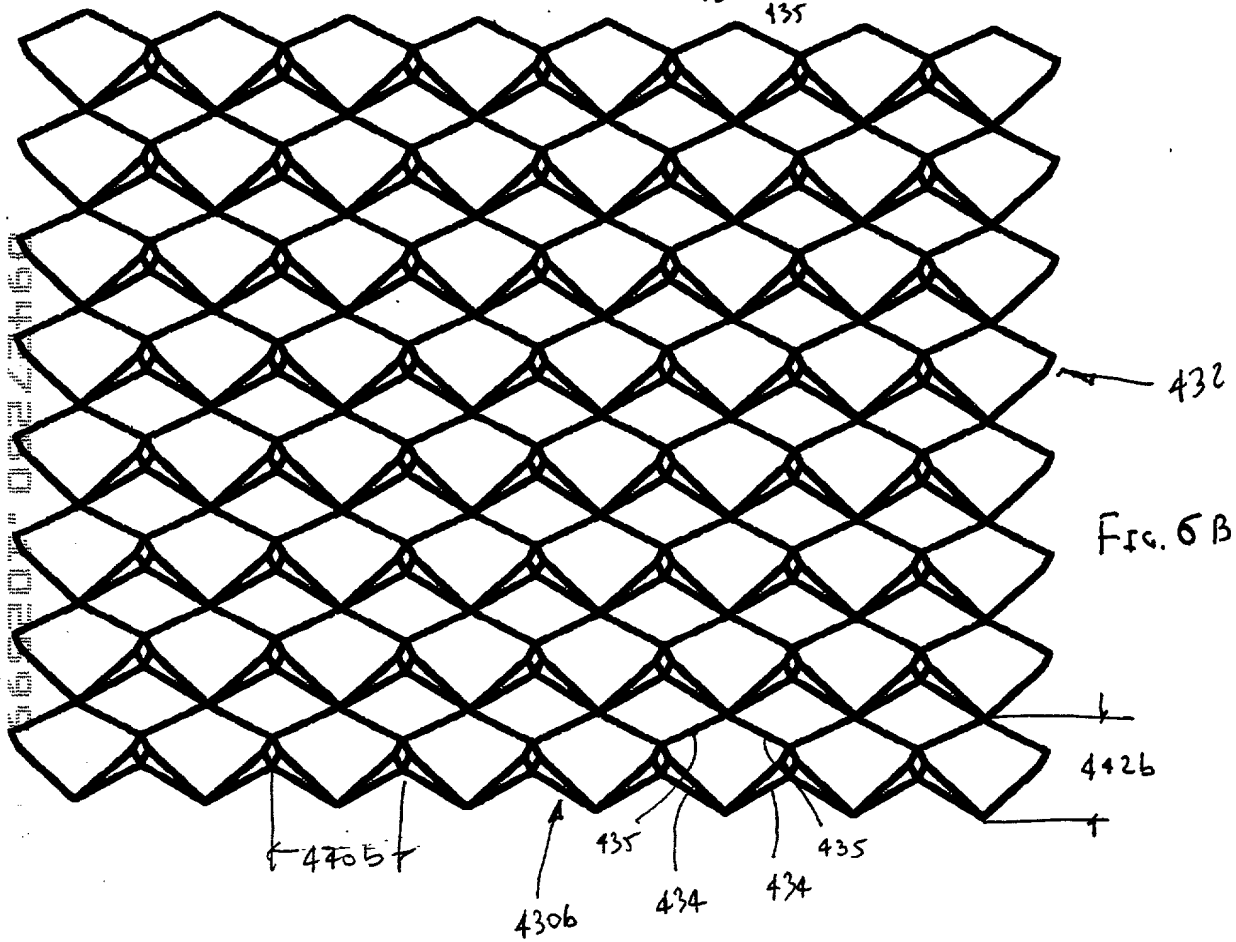
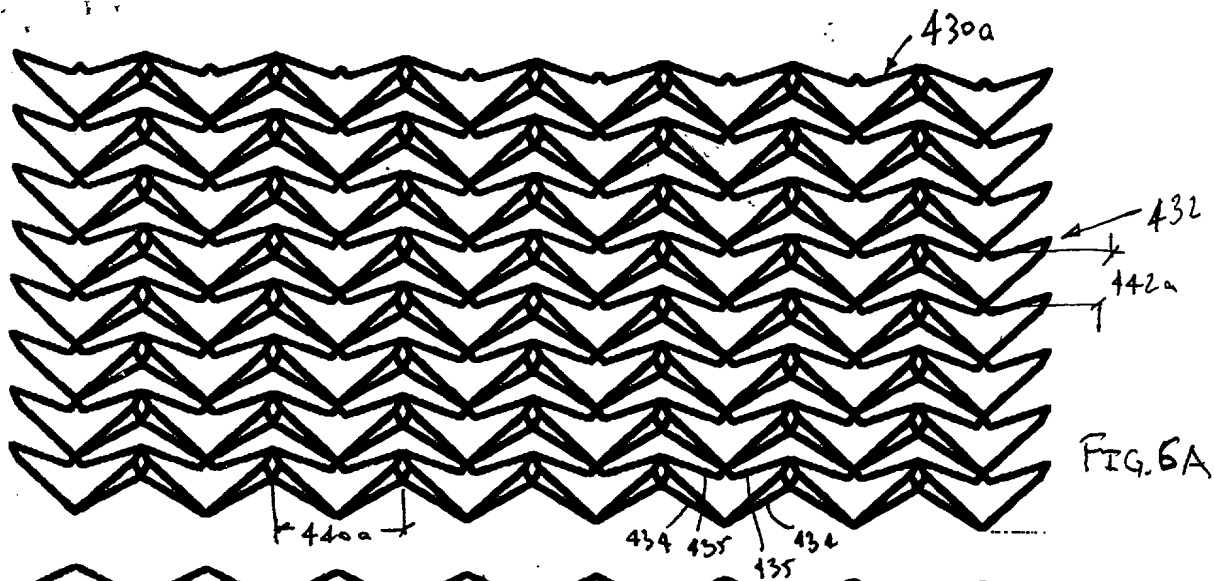


FIG. 2B

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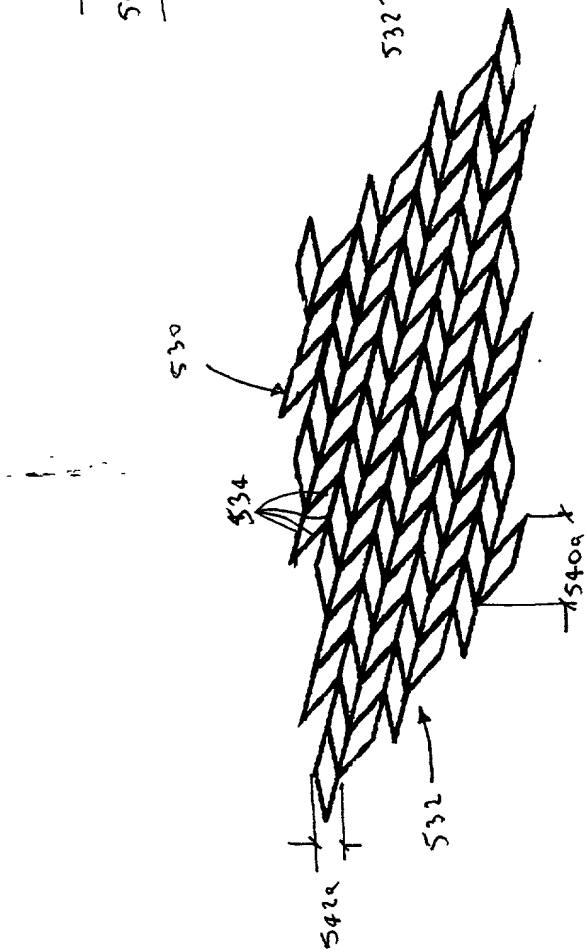


FIG. 7A

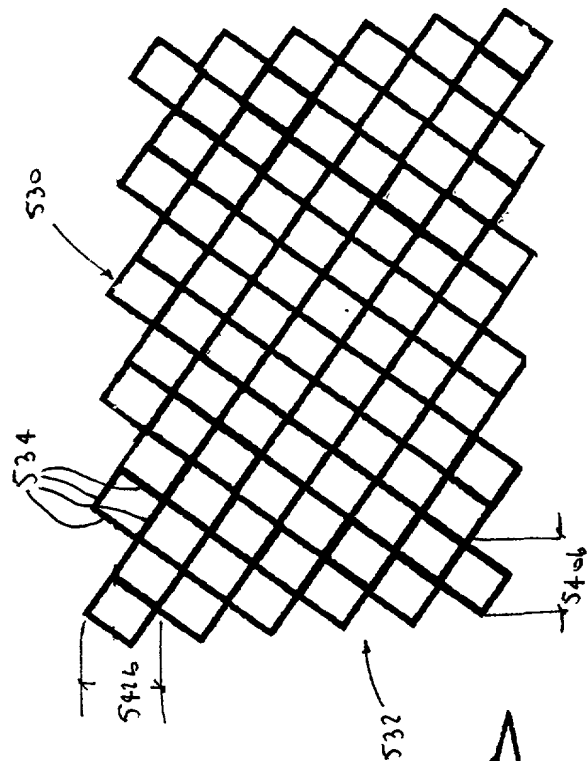


FIG. 7B

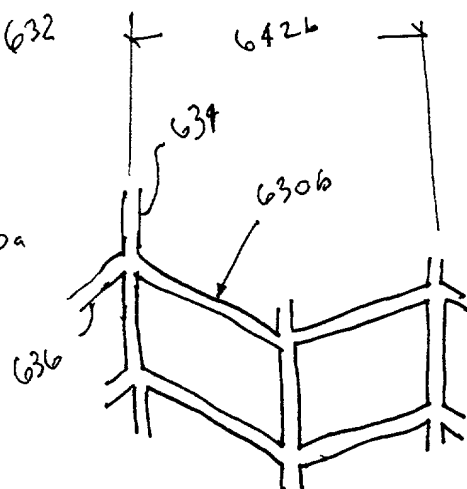
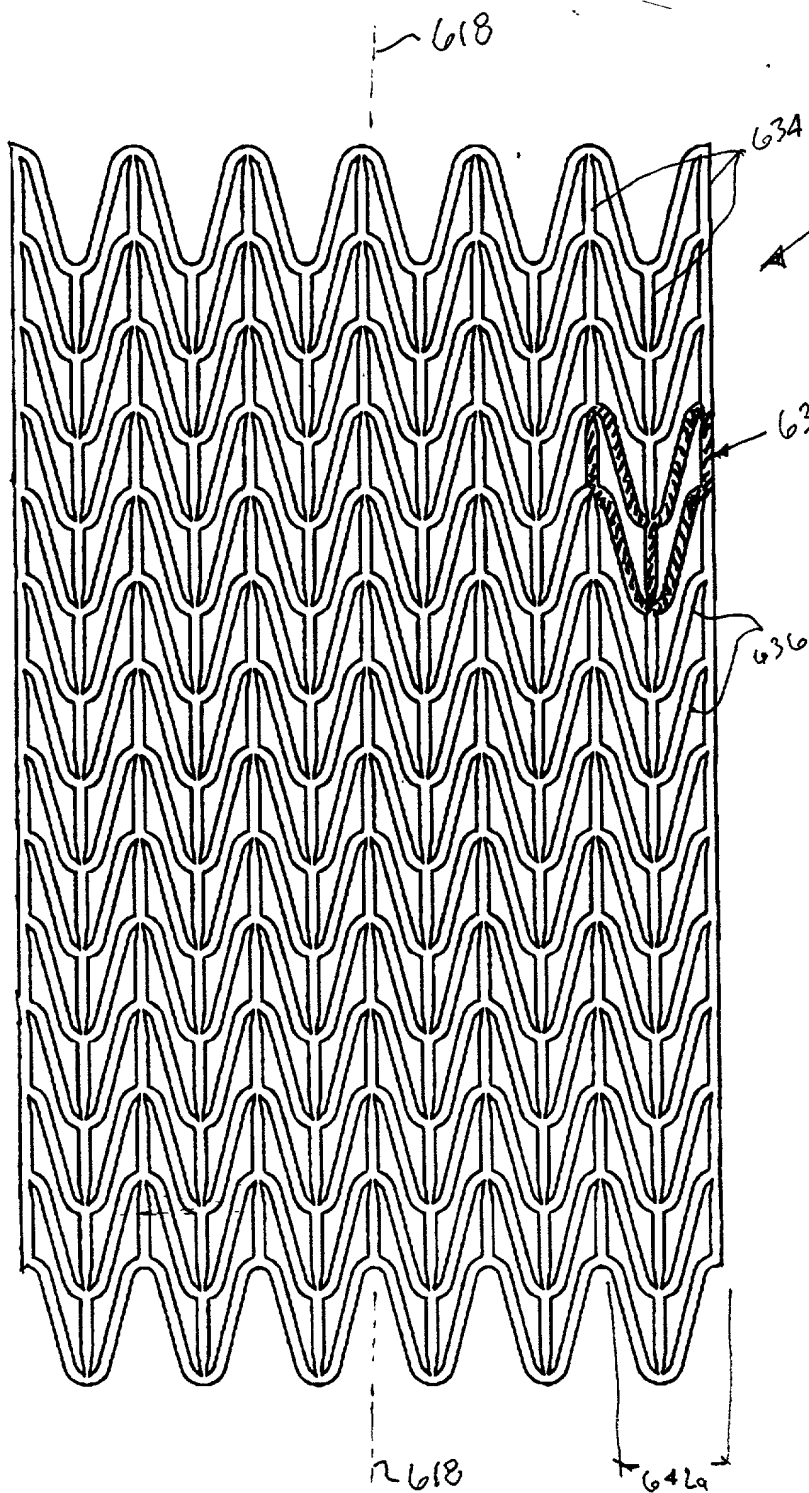


FIG. 8A

FIG. 8B

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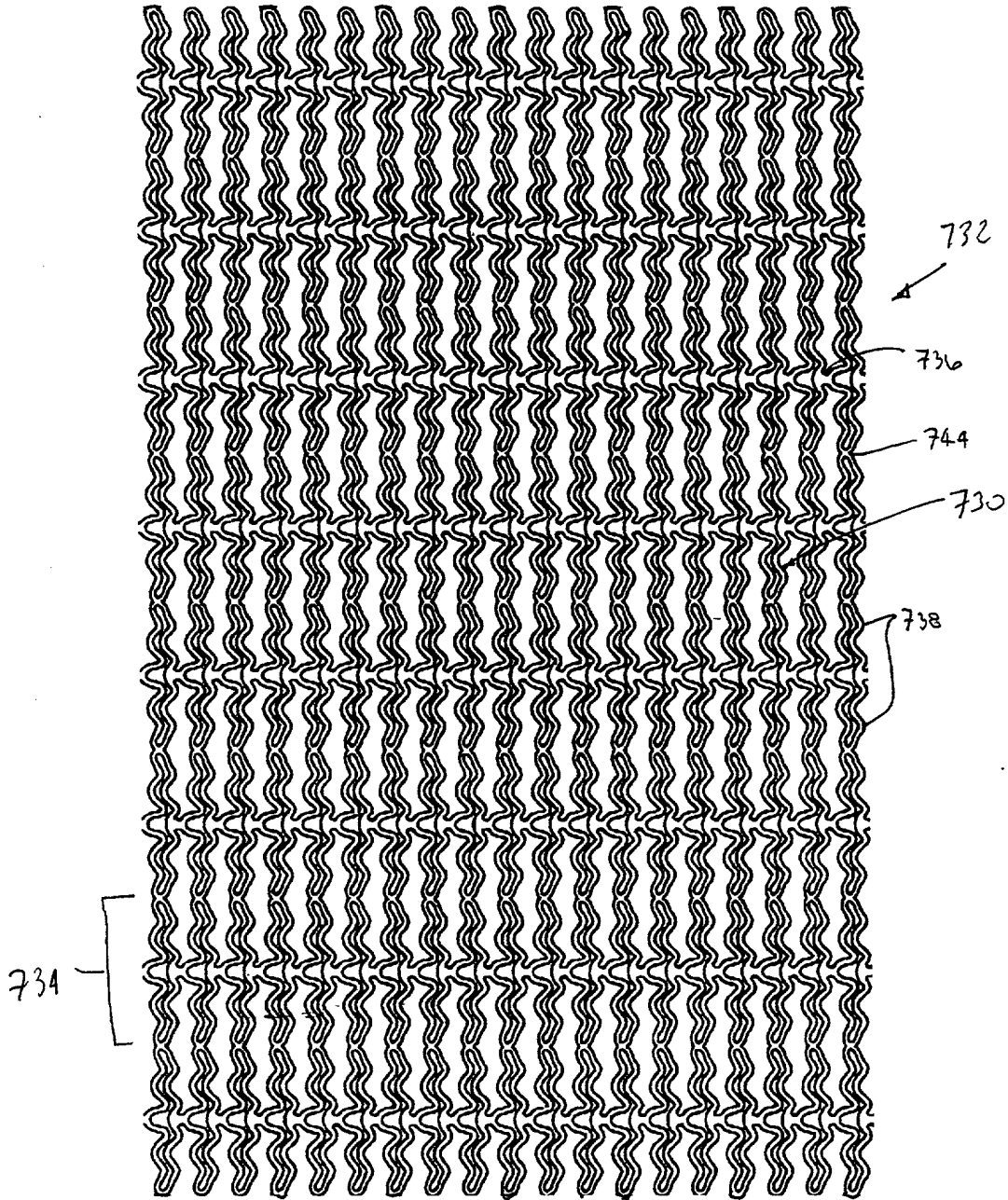


Fig. 9

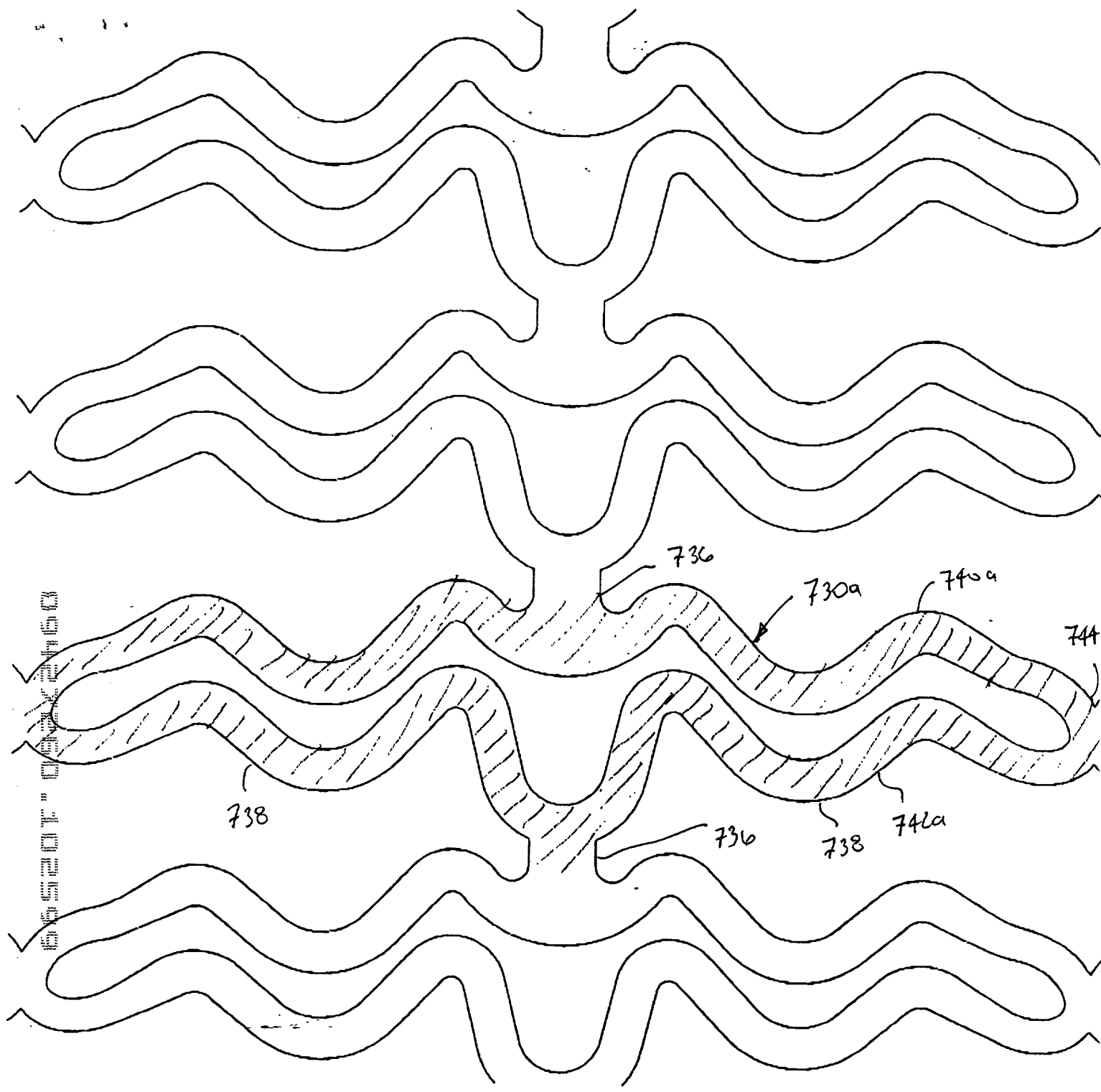


FIG. 10A

0942760-10269

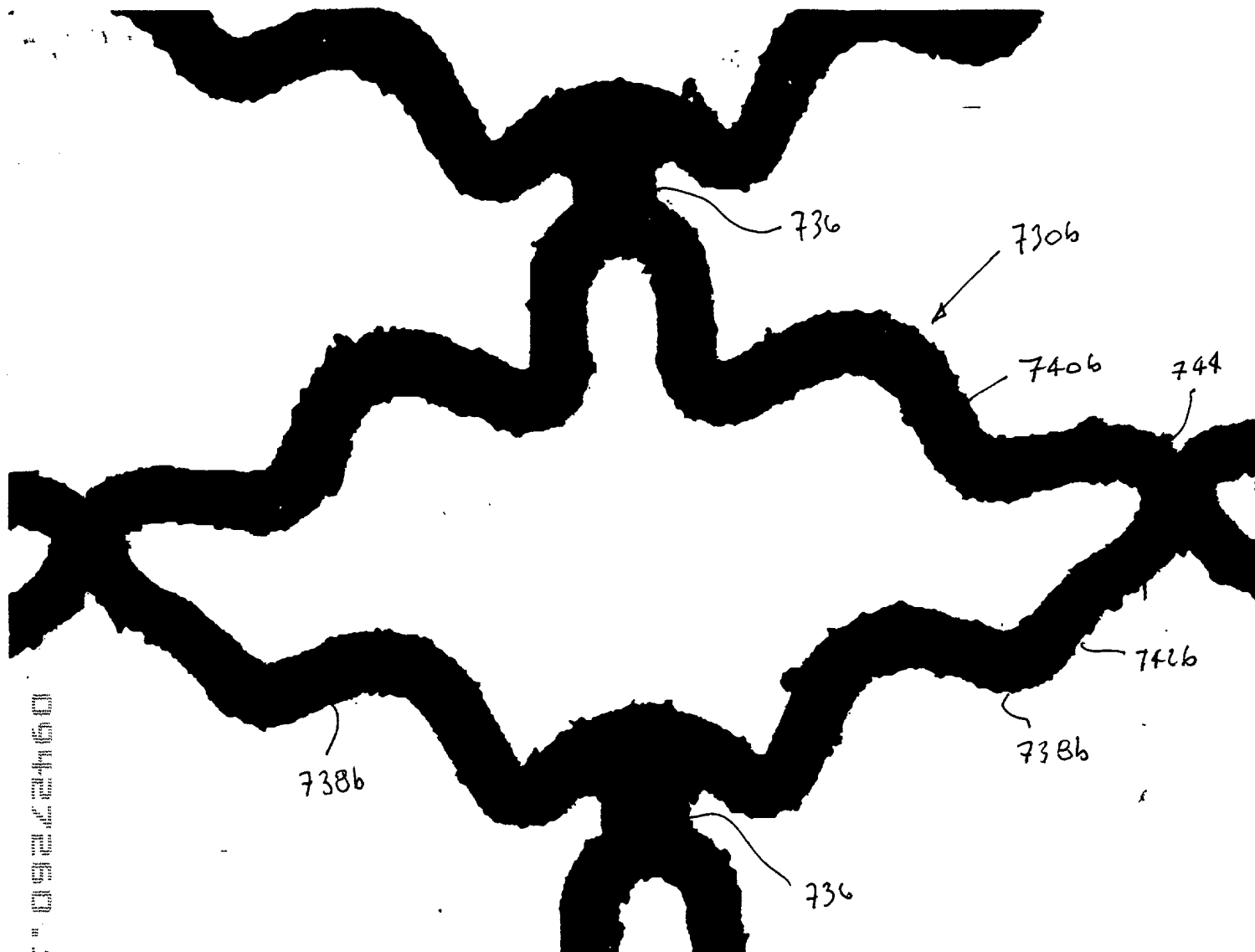


FIG. 10B

094270-10369

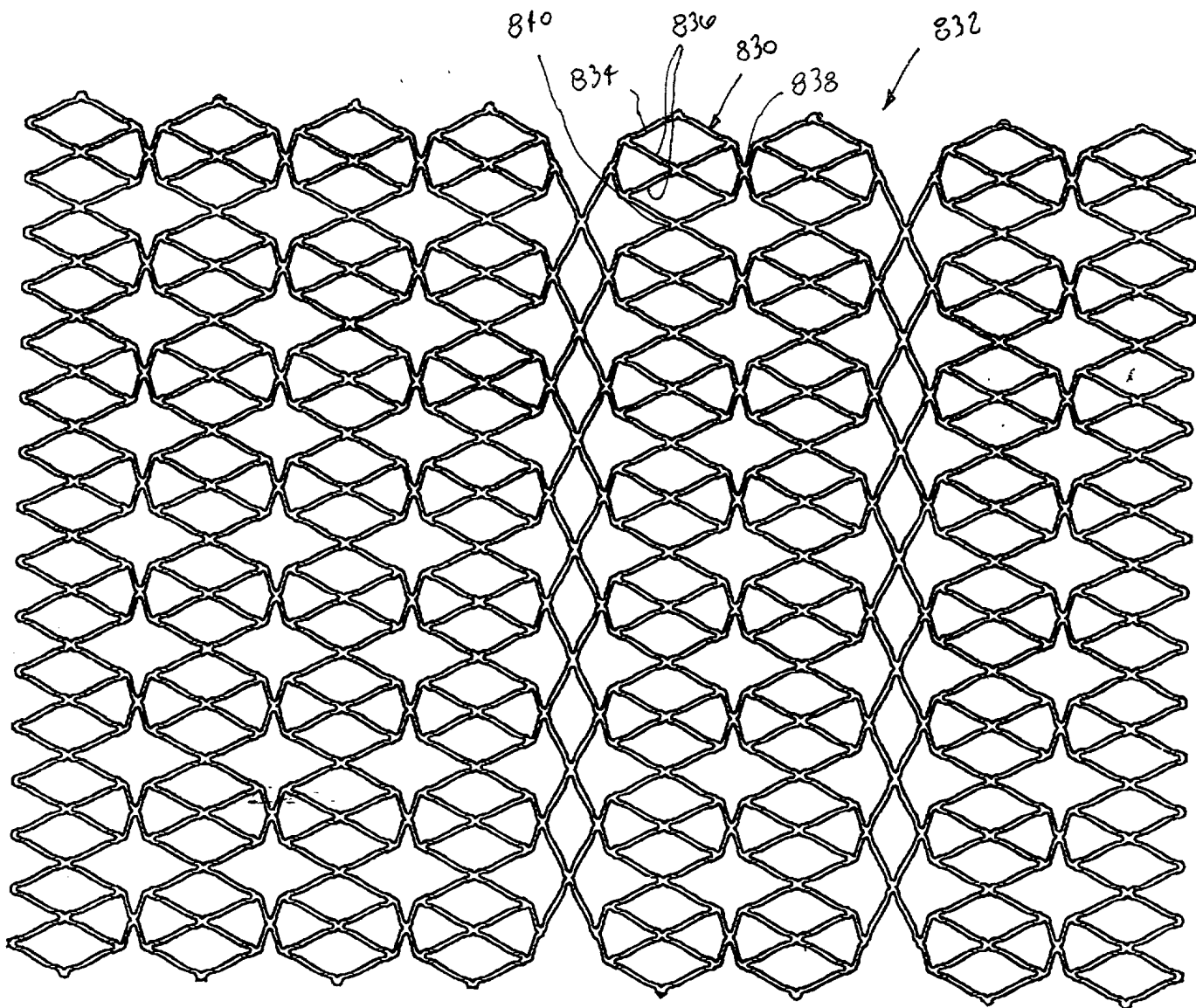


FIG. 11

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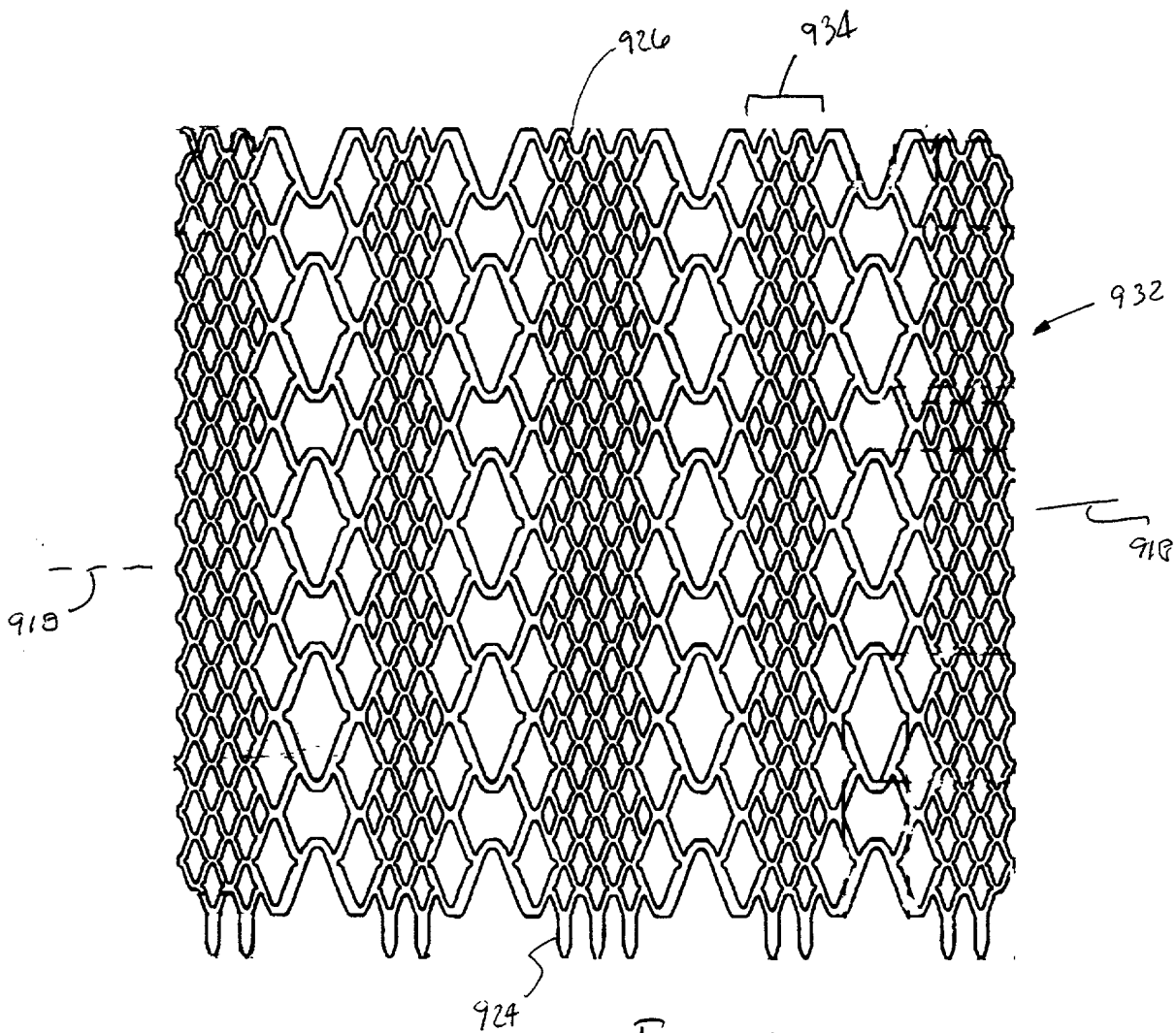


FIG. 12

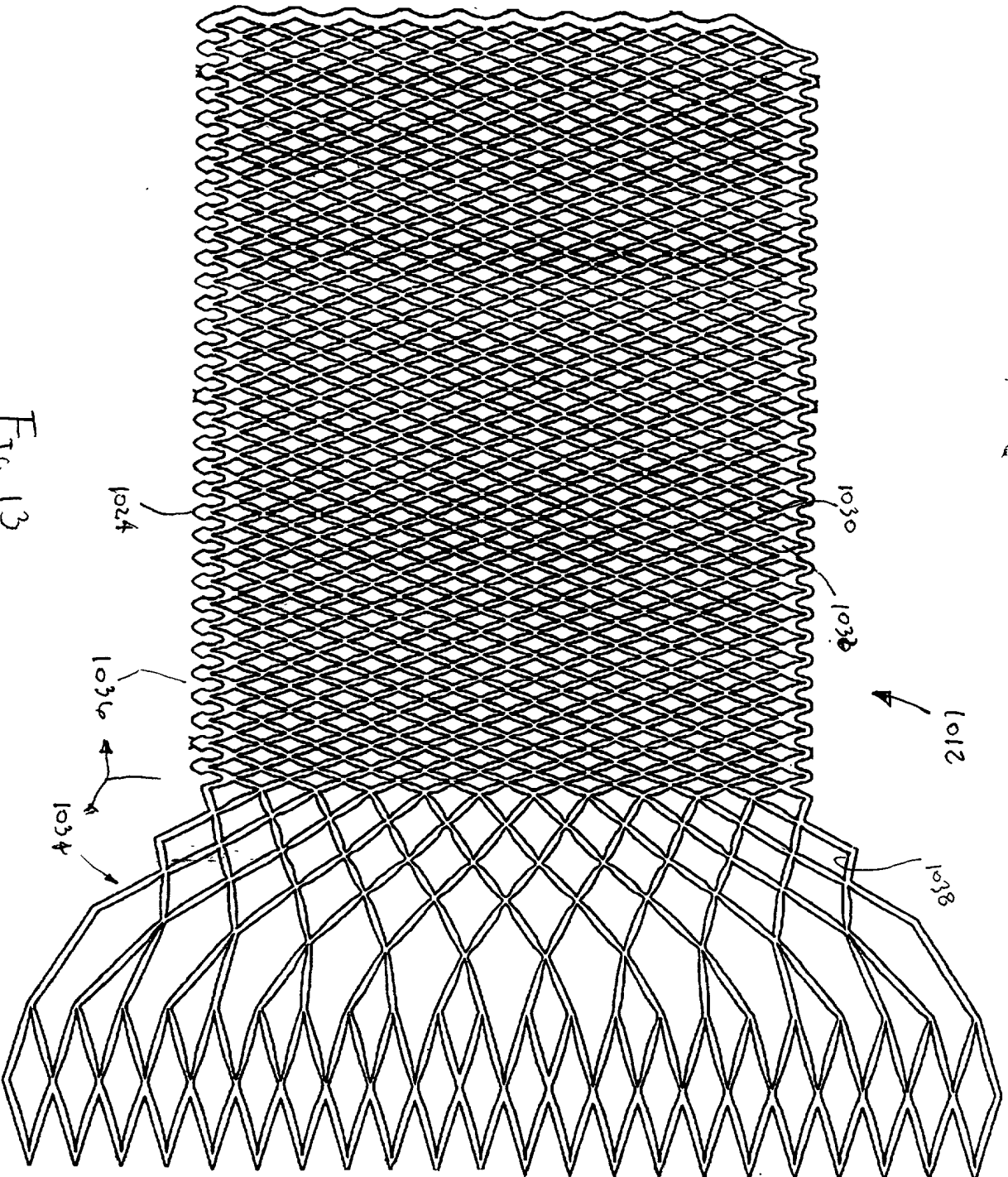


FIG. 13

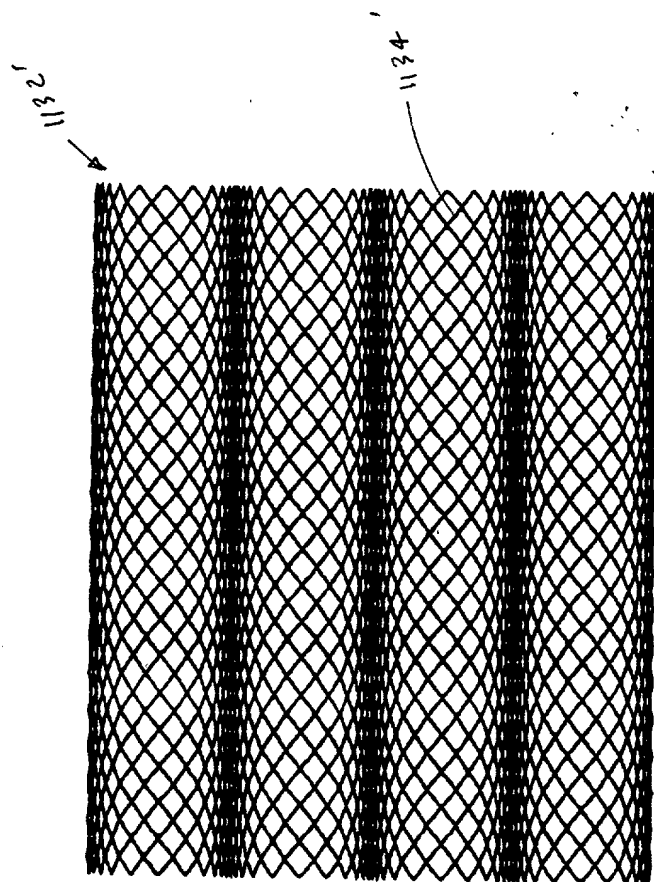


FIG. 14B

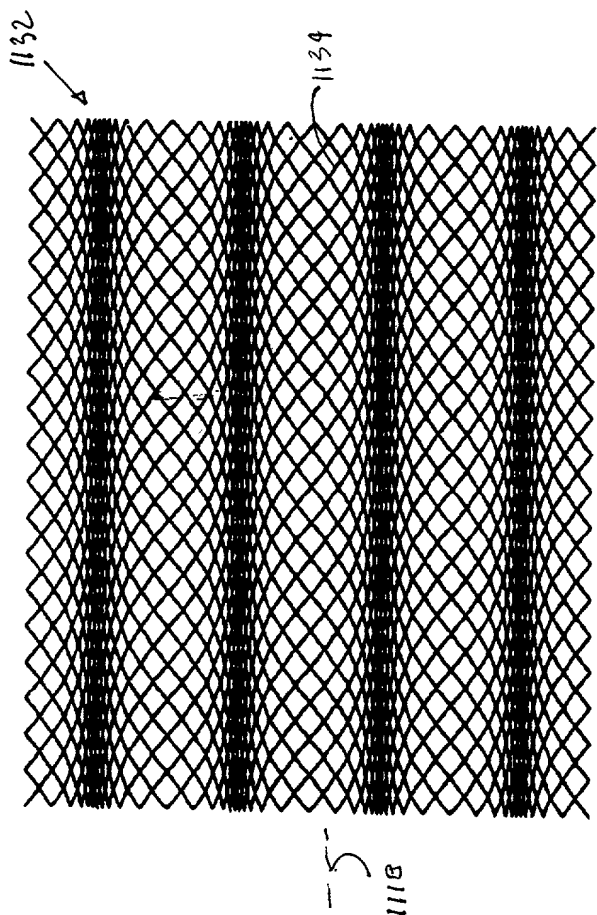


FIG. 14A

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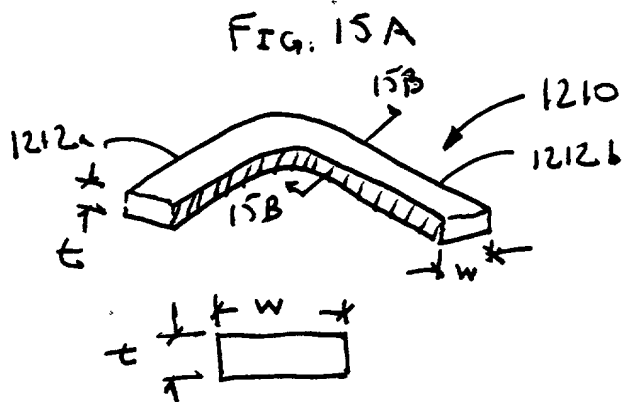


FIG. 15B

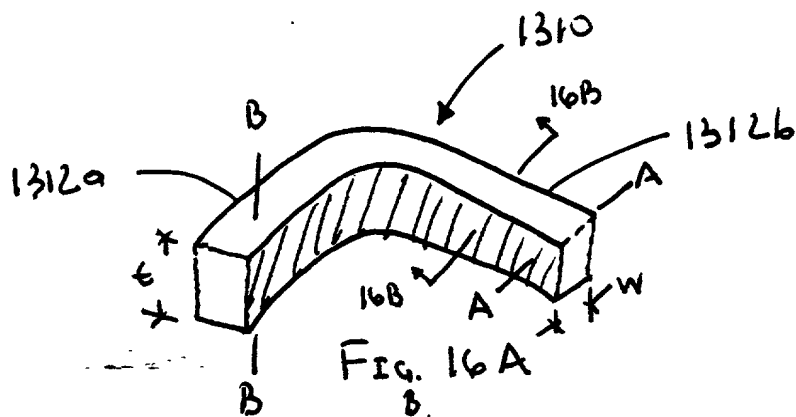
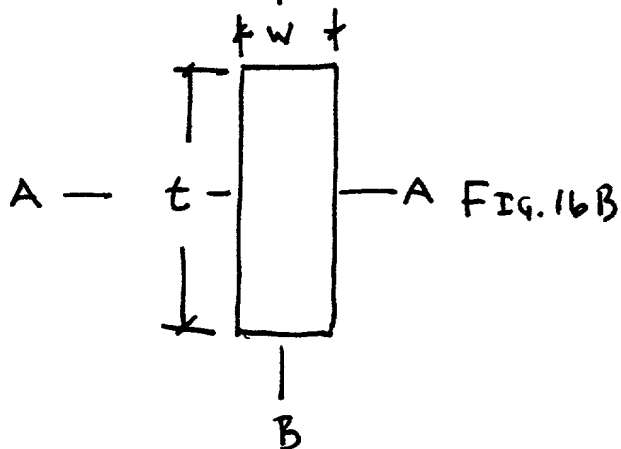
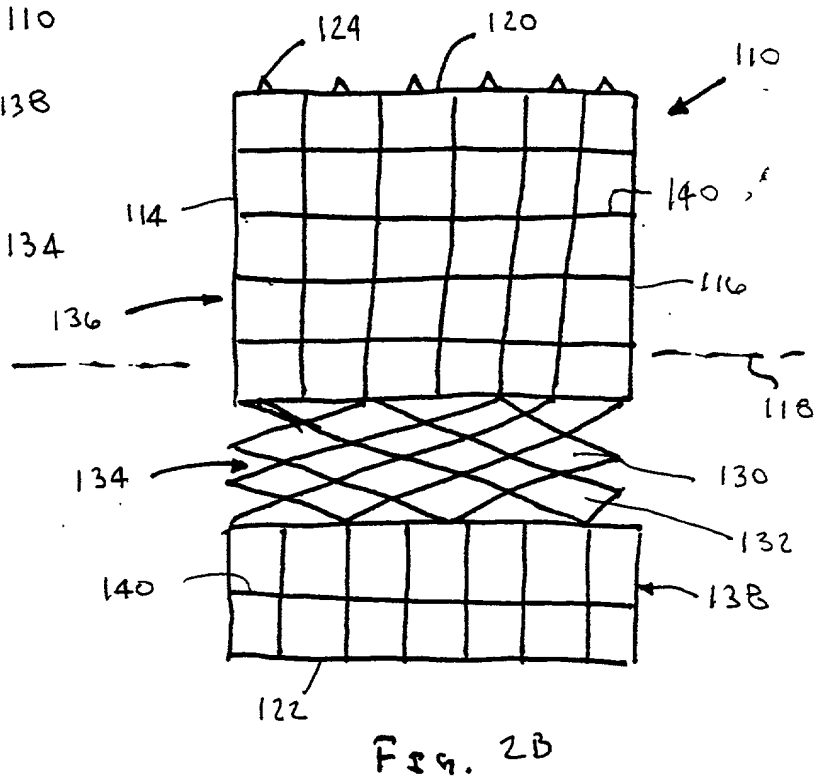
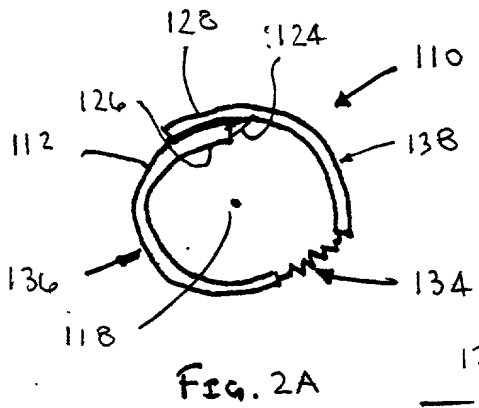
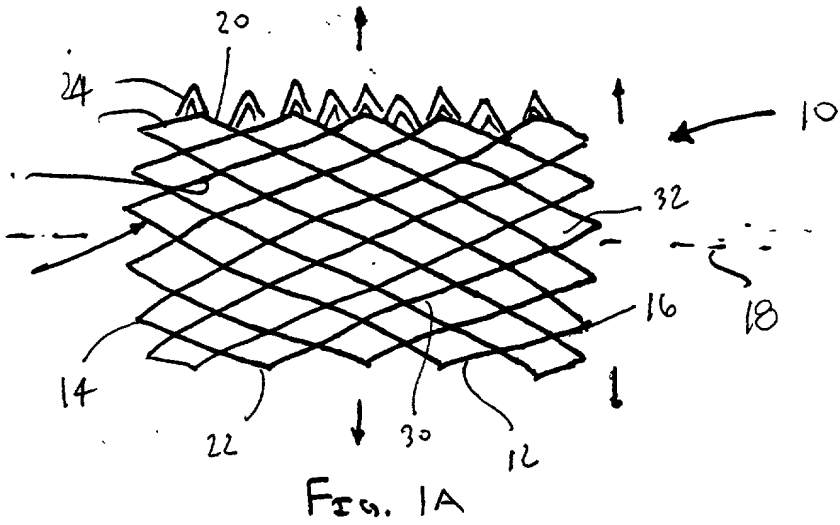
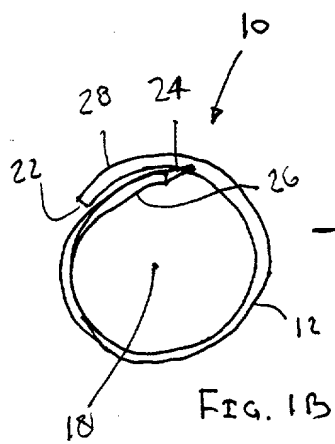
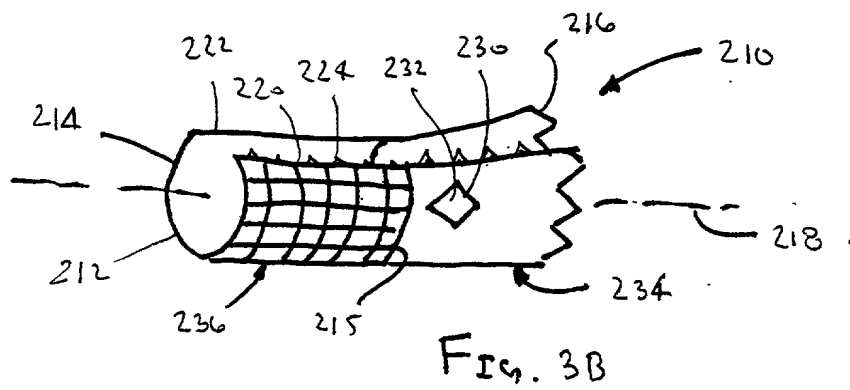
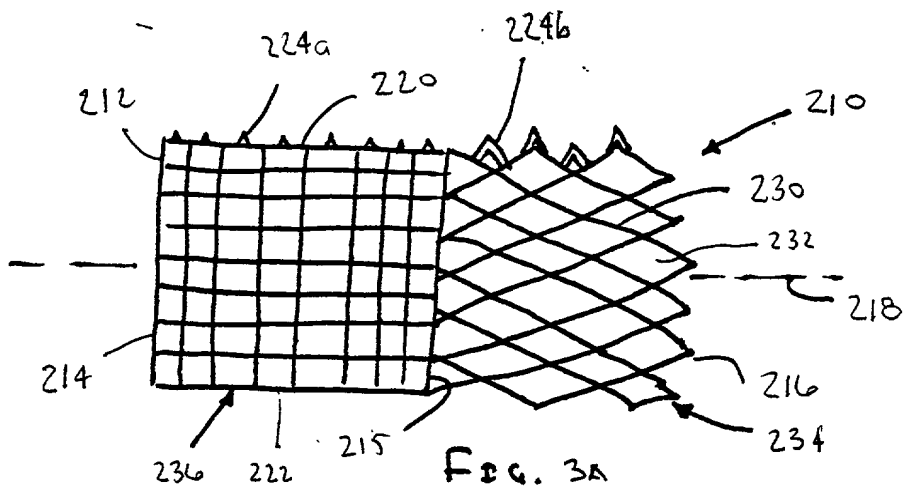


FIG. 16A





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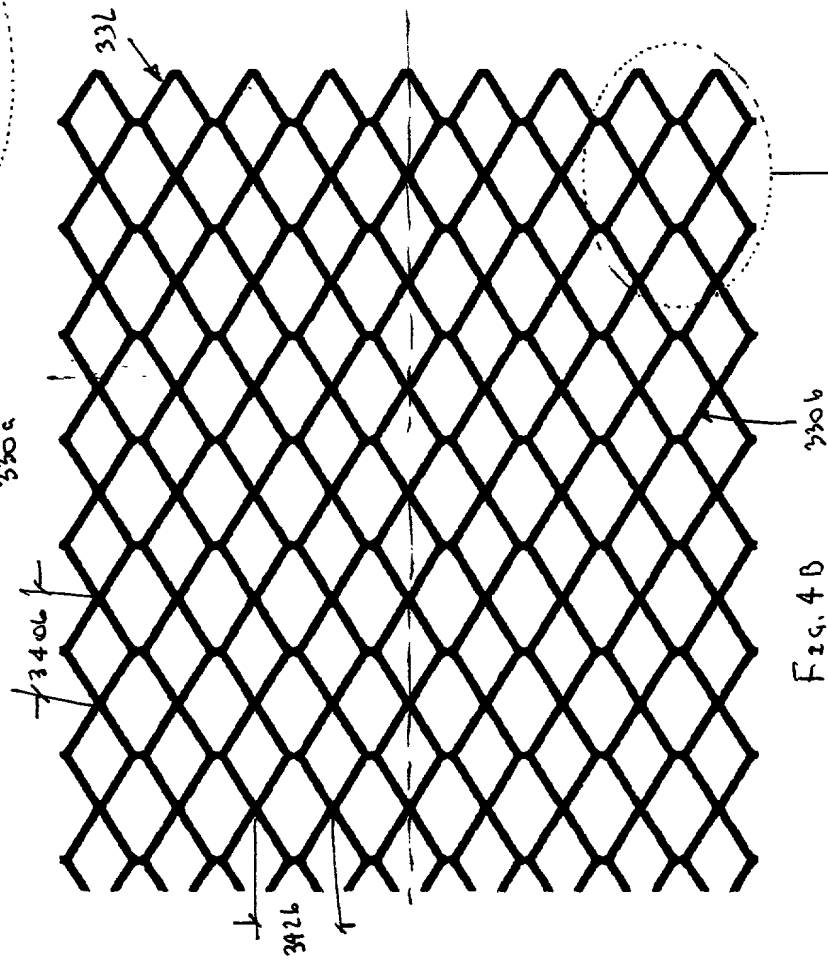
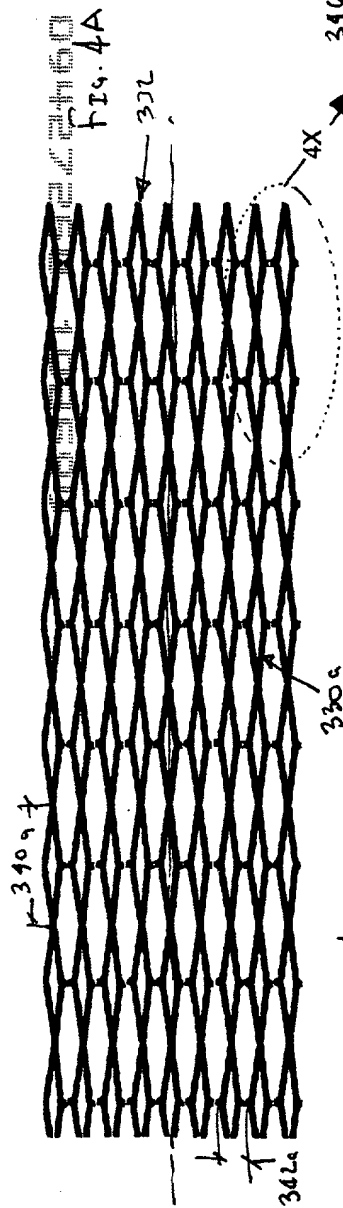


Fig. 5A

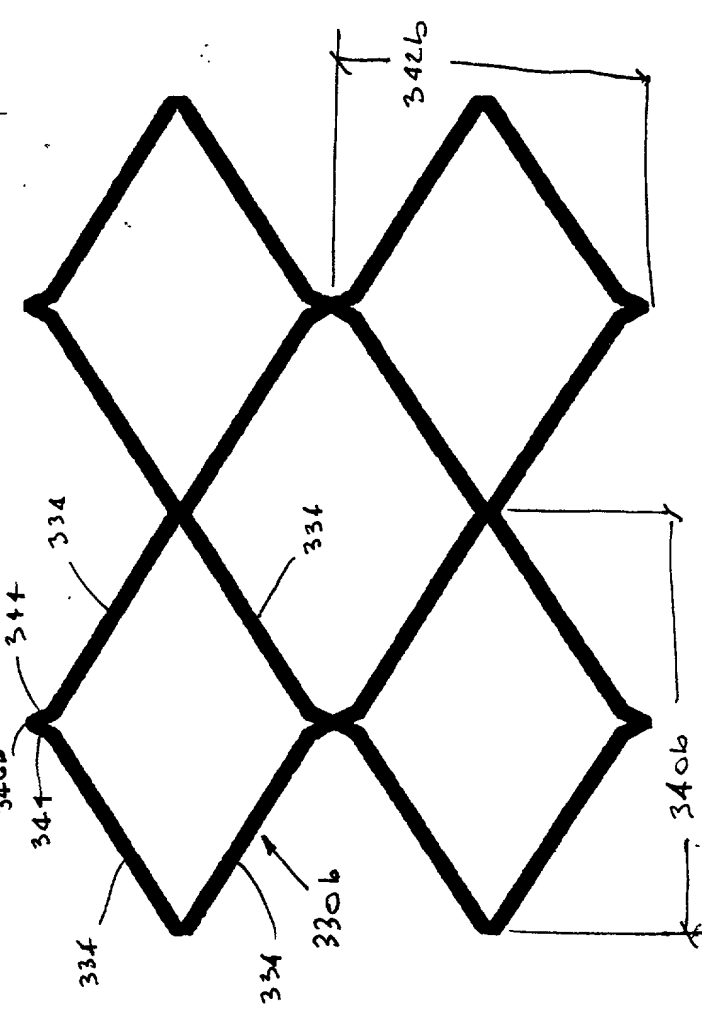
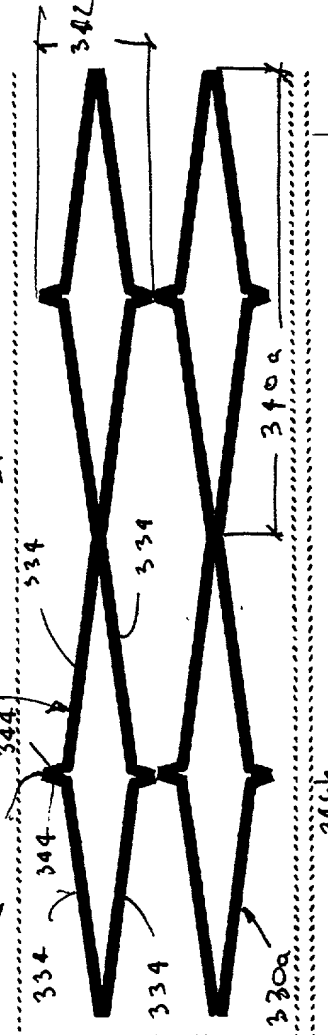


Fig. 5B

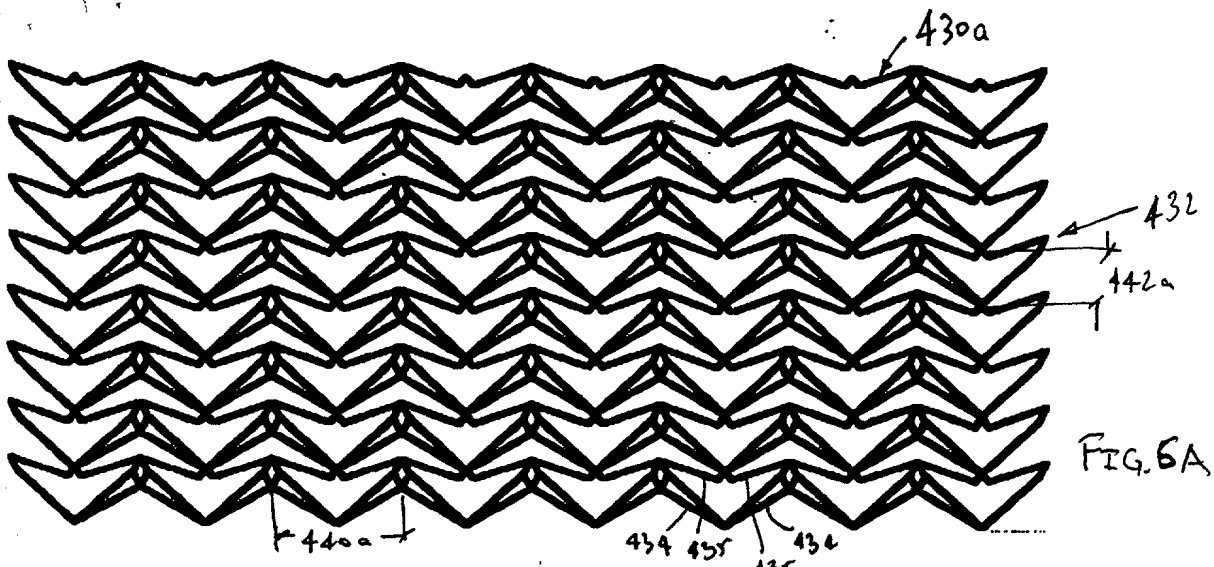


FIG. 6A

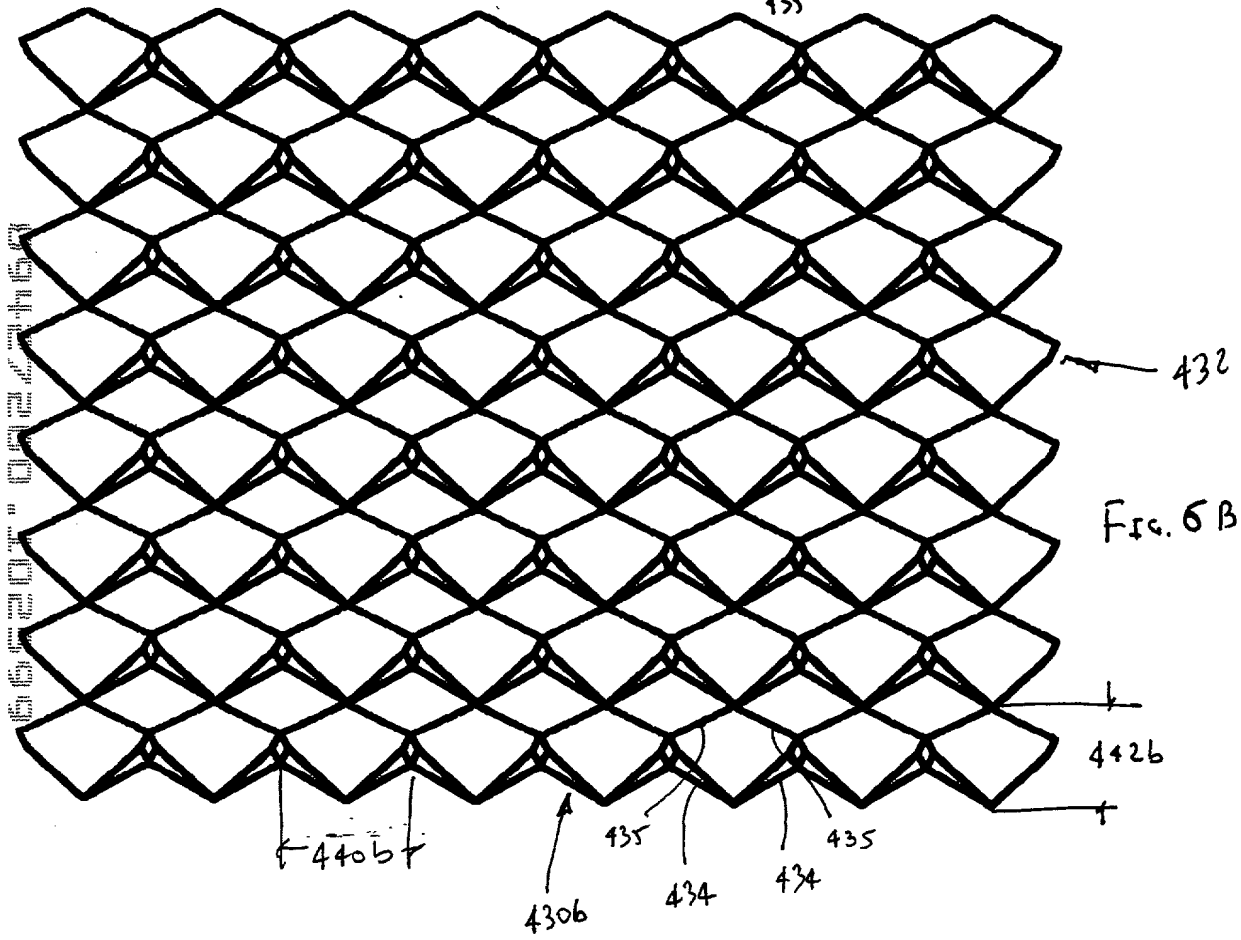


FIG. 6B

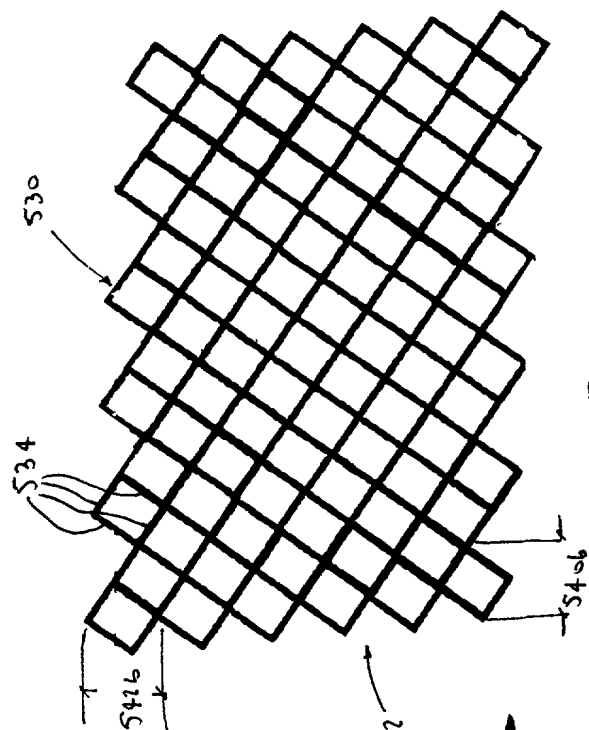


Fig. 7B

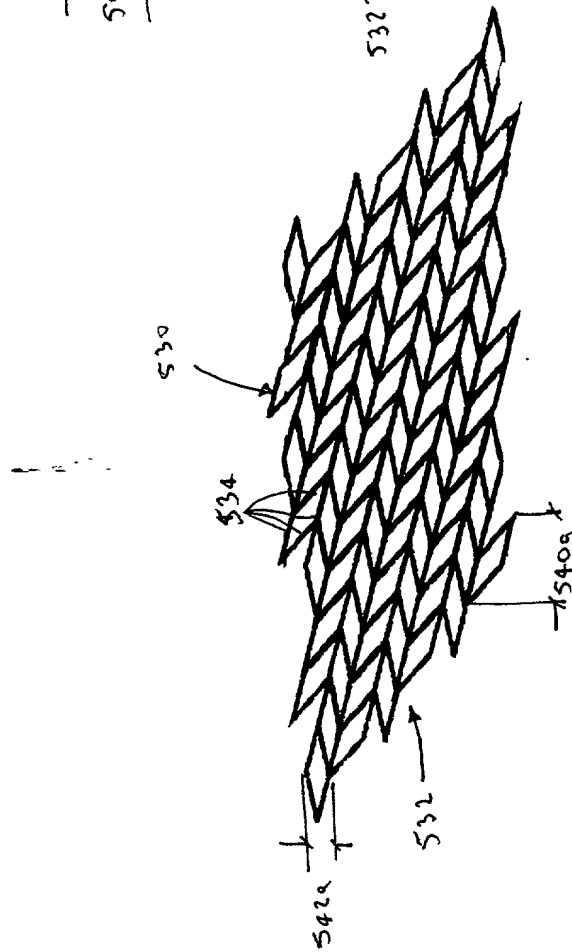


Fig. 7A

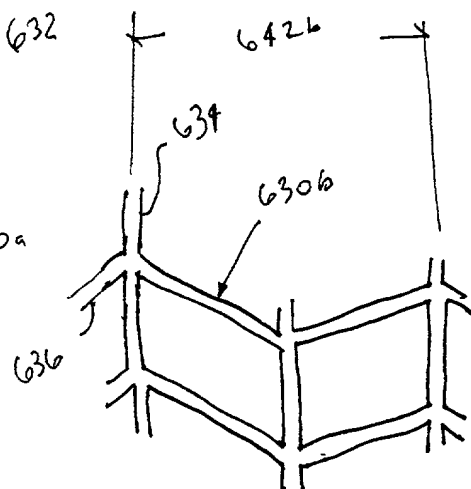
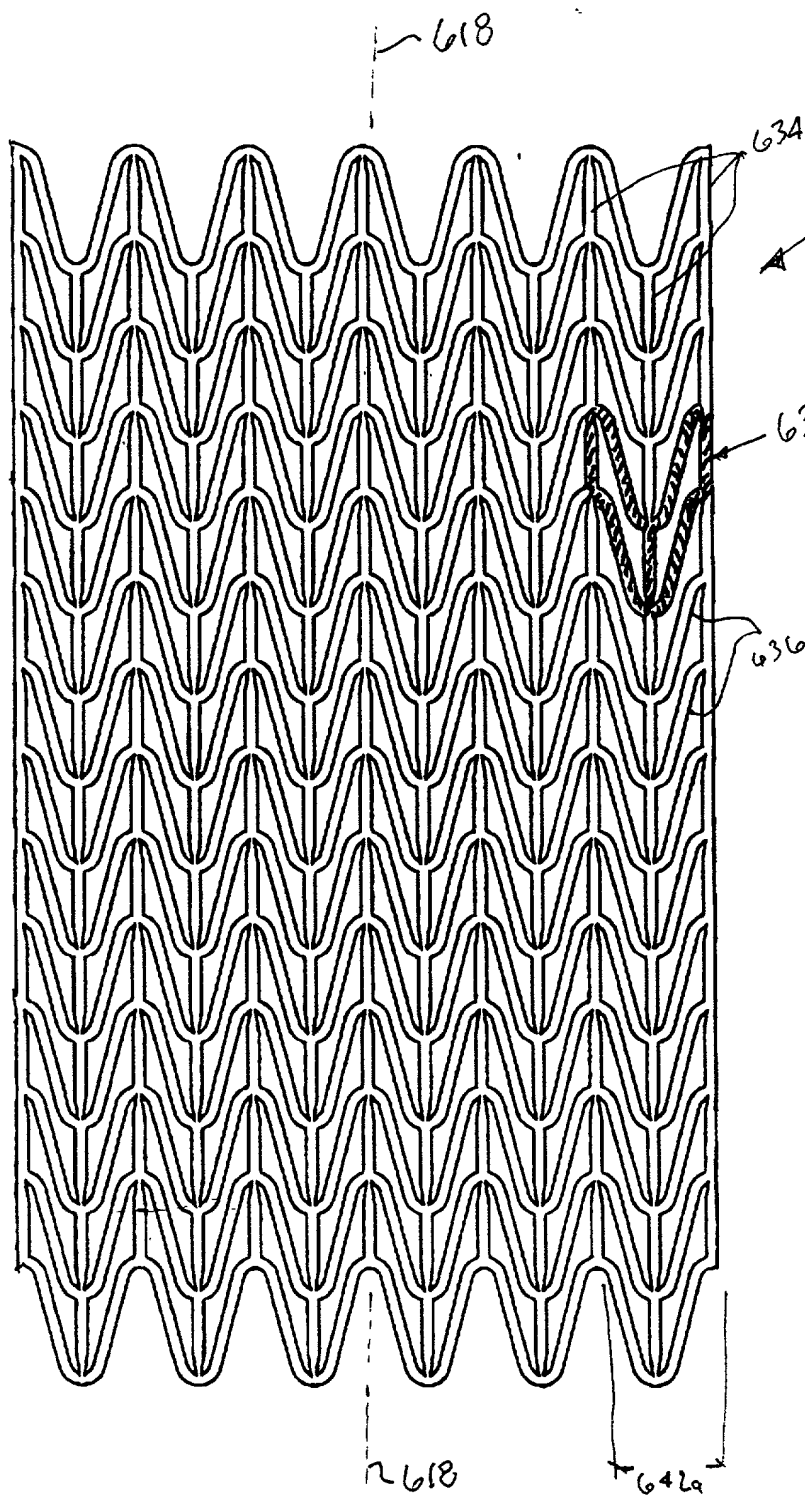


FIG. 8B

FIG. 8A

655207-032460

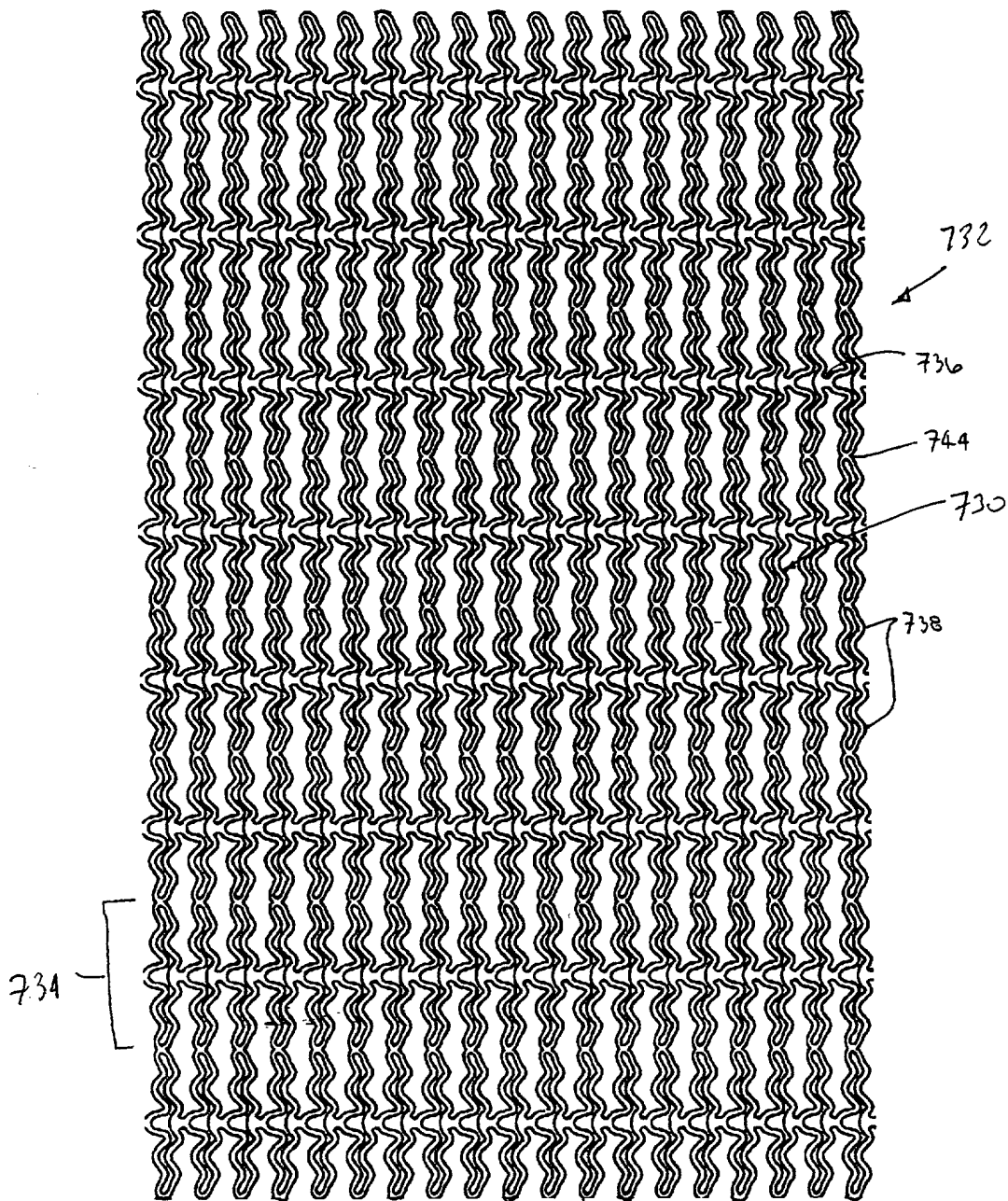


Fig. 9

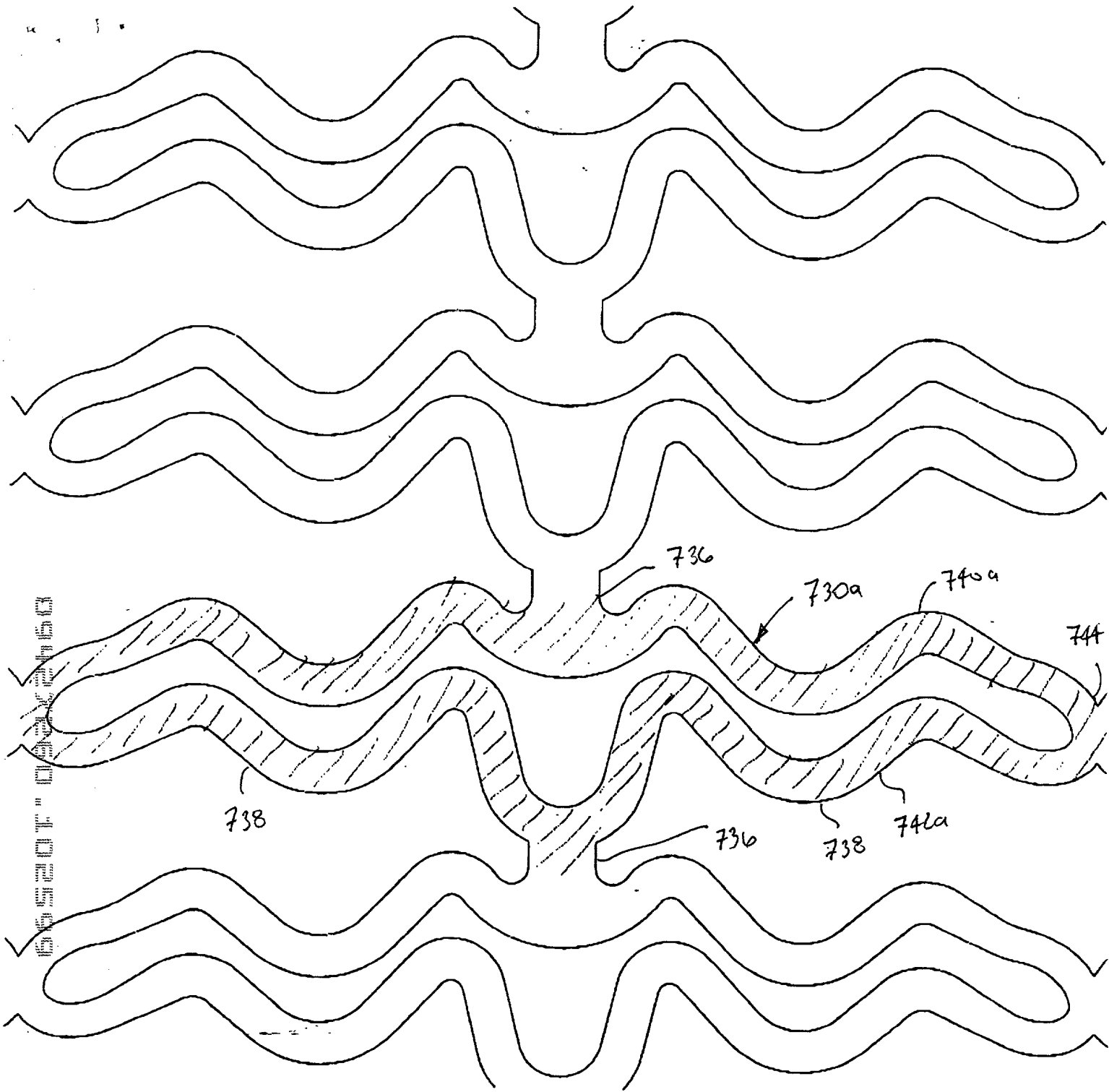


FIG. 10A

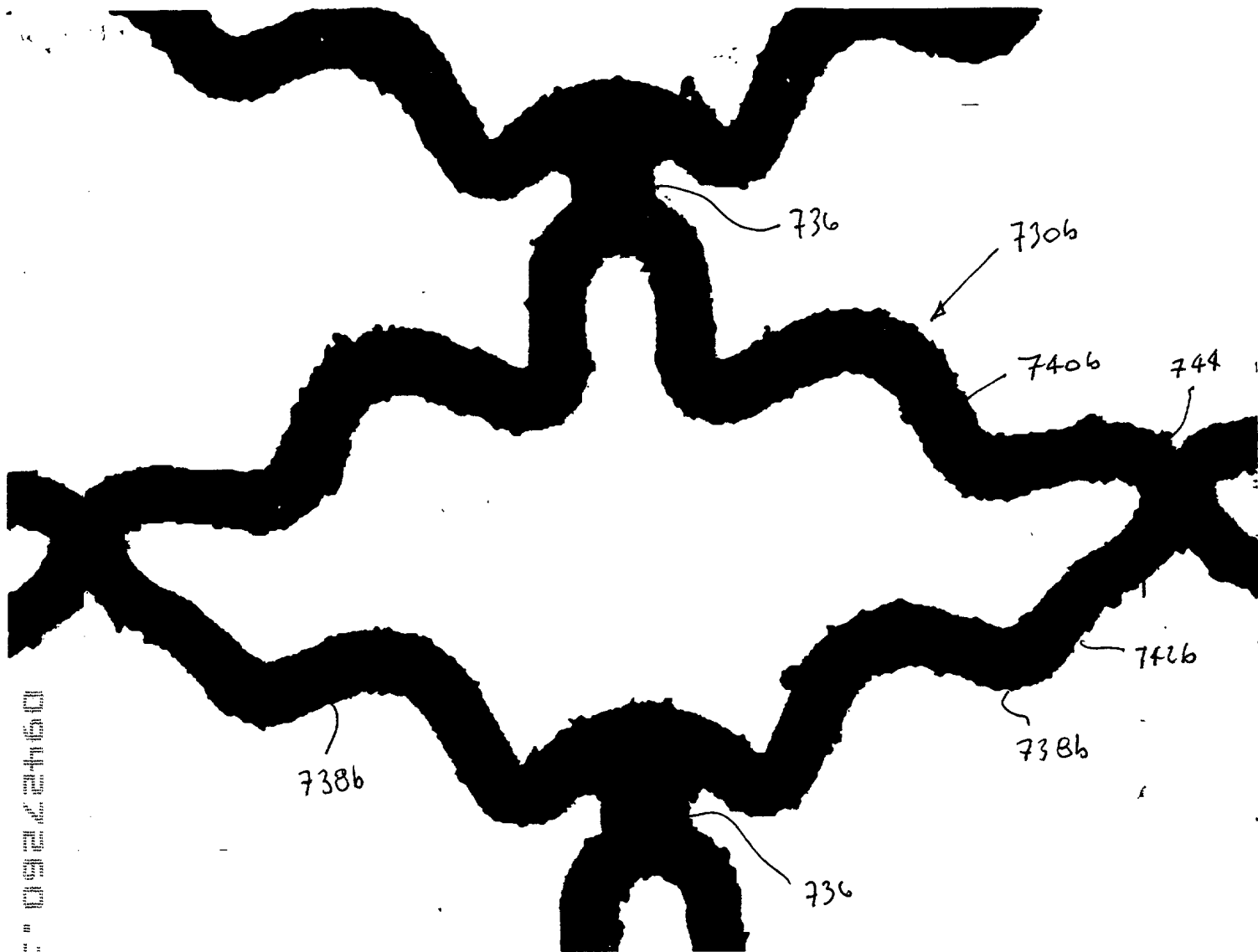


FIG. 10B

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0342760 4032460

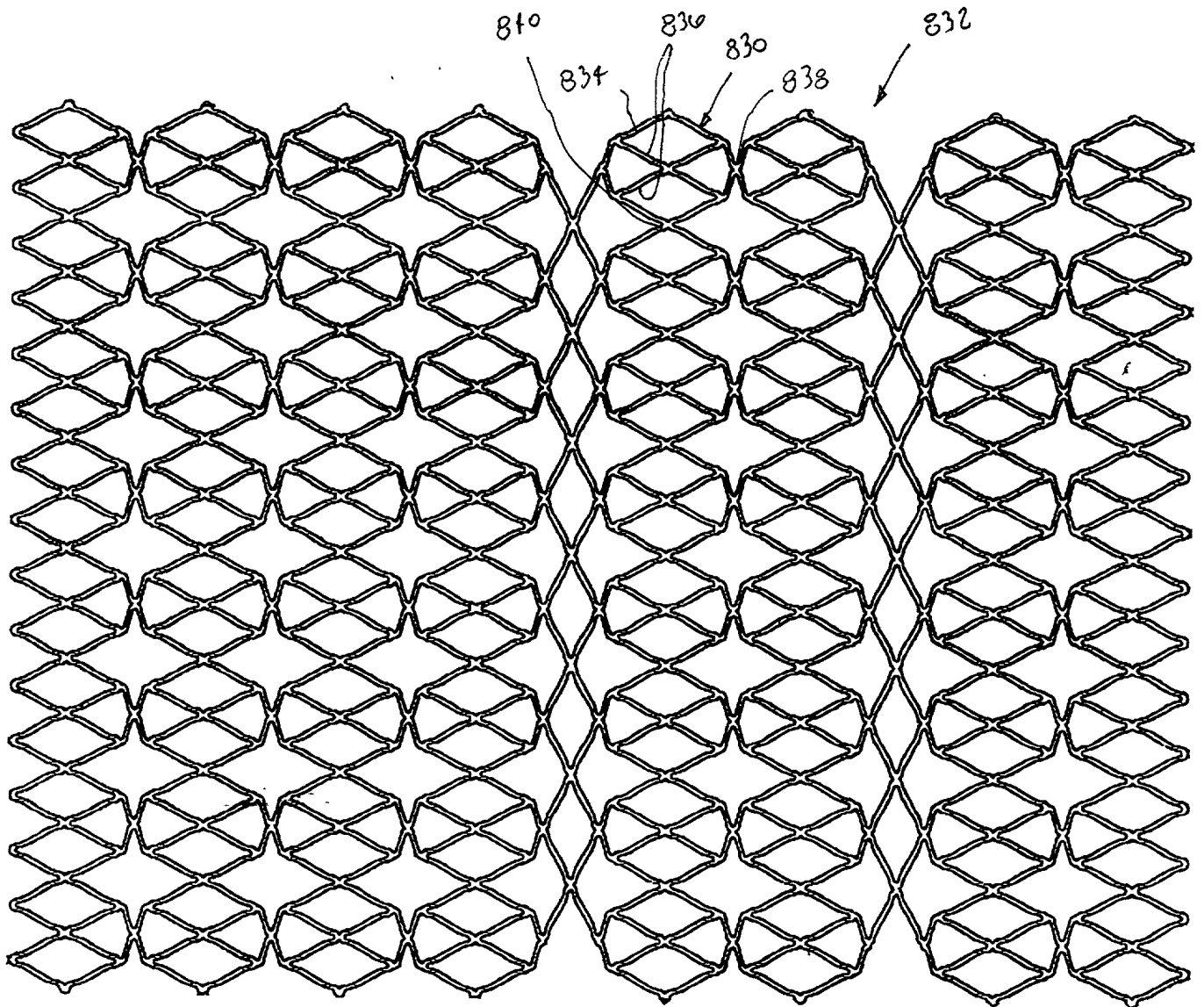


FIG. 11

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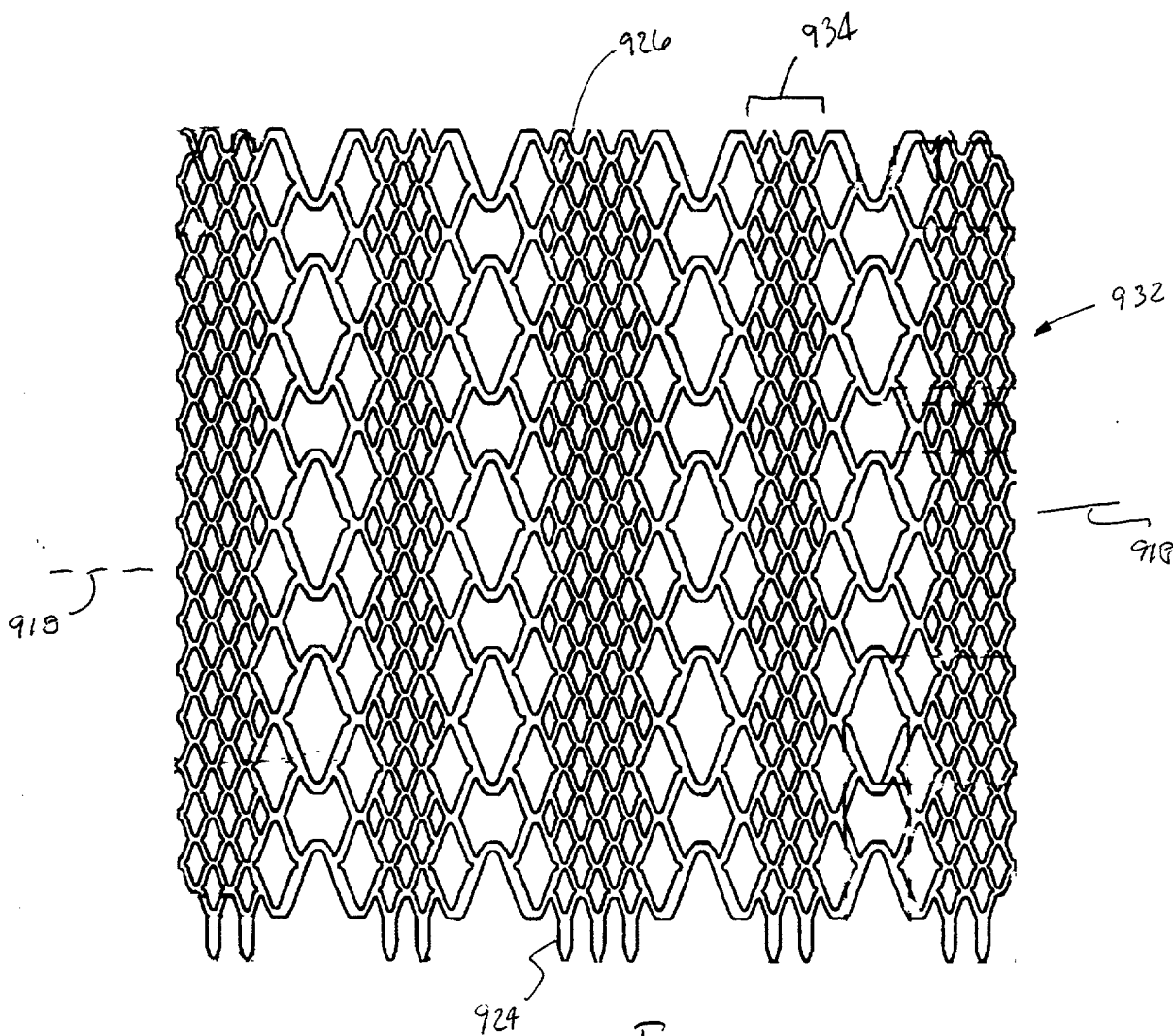


FIG. 12

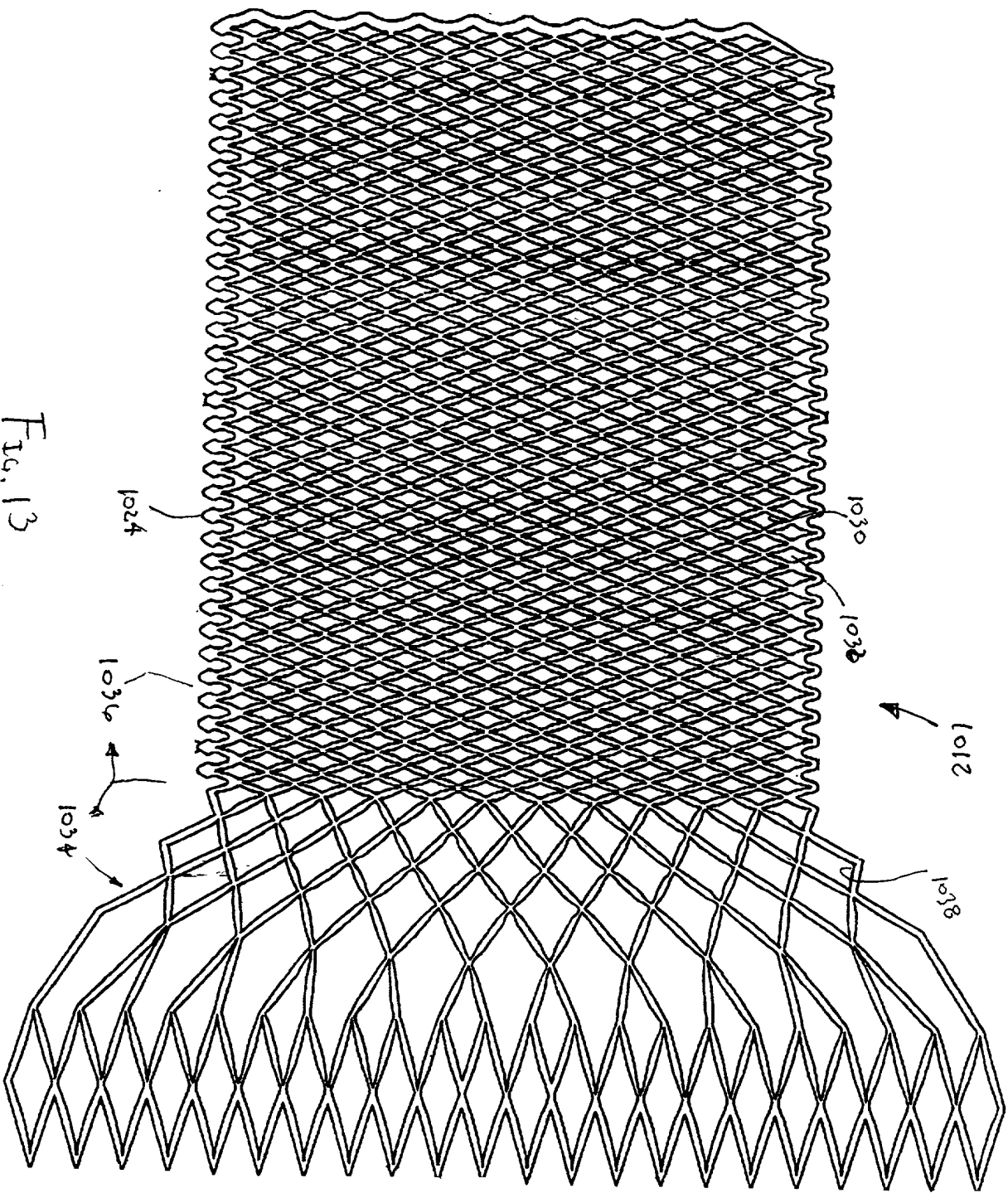


FIG. 13

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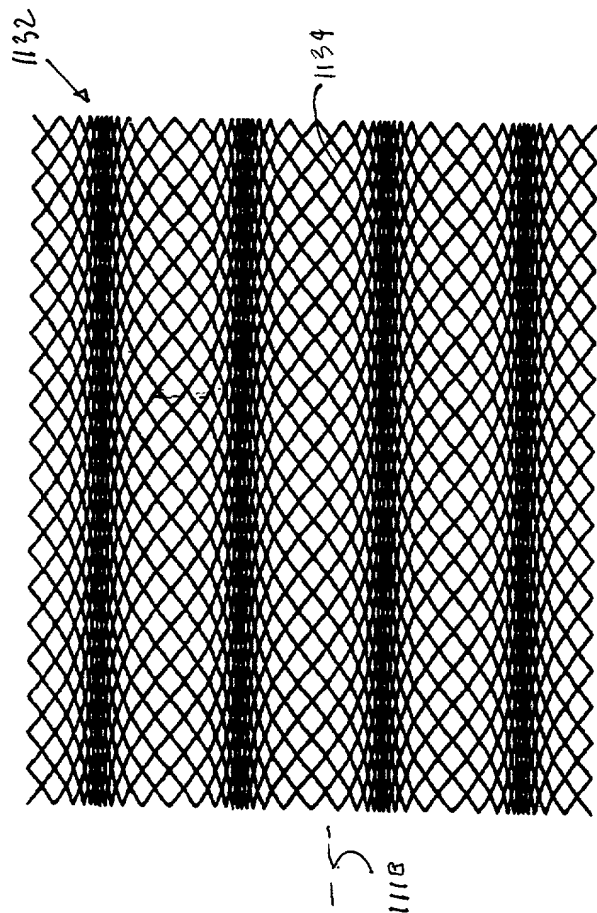


FIG. 14A

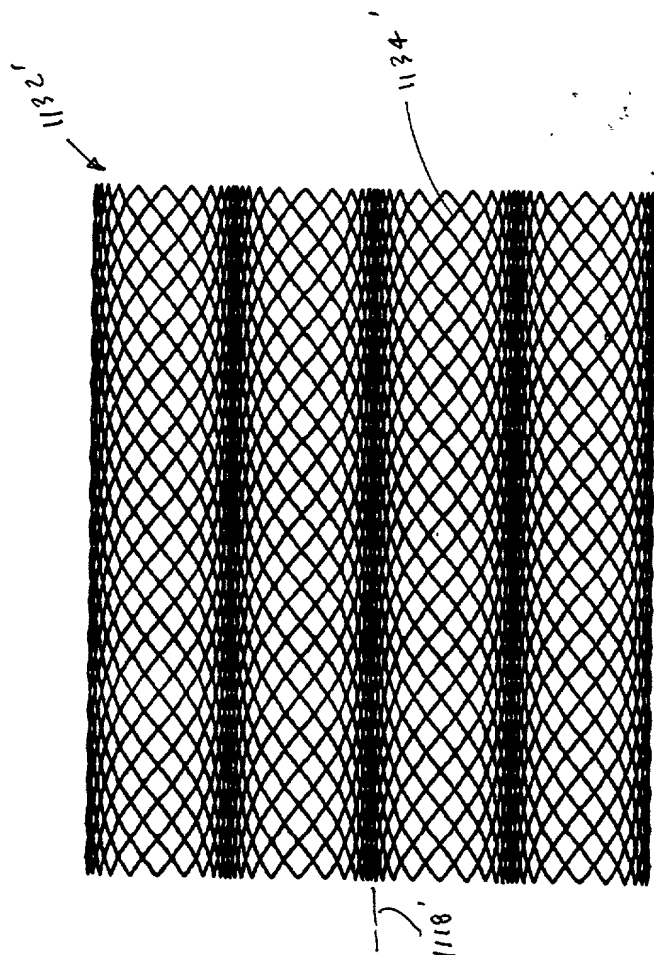


FIG. 14B

FIG. 15A

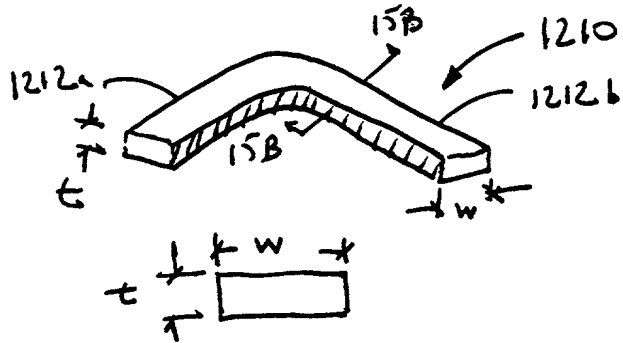


FIG. 15B

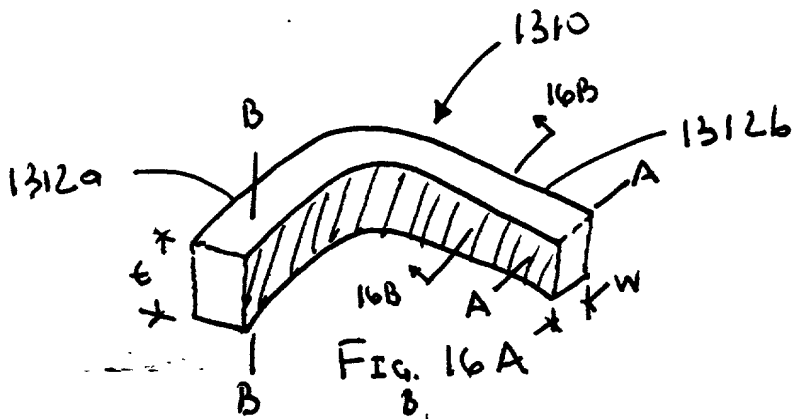


FIG. 16A

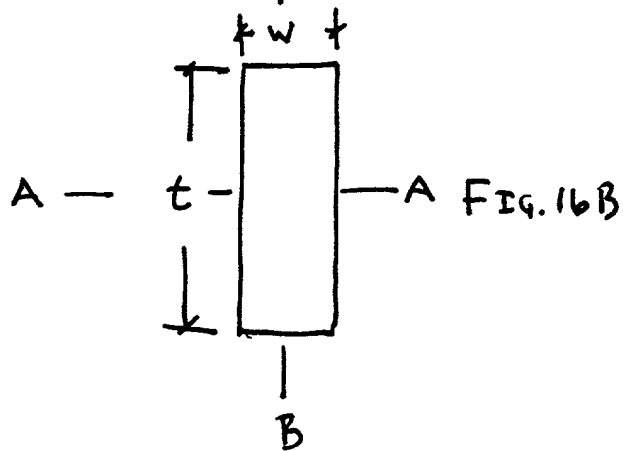


FIG. 16B

DECLARATION
Utility Application

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **STRETCHABLE ANTI-BUCKLING COILED-SHEET STENT** the specification of which

(Check One) ☒ is attached hereto OR
☐ was filed on _____ as United States Application Serial No. SerialNumber or PCT International Application No. _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Date of Filing	Priority Claimed	
			Yes	No

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

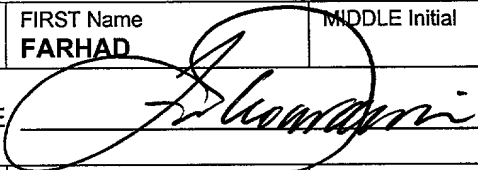
Application Number(s)	Filing Date


I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date	Status-Patented, Pending or Abandoned
09/192,977		November 16, 1998	pending

Send Correspondence to: WILLIAM A. ENGLISH	LYON & LYON LLP 633 W Fifth St., Suite 4700 Los Angeles, CA 90071	Direct Telephone calls to: (714) 751-6606
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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

	FULL NAME OF INVENTOR	FIRST Name FARHAD	MIDDLE Initial	LAST Name KHOSRAVI	
INVENTOR'S SIGNATURE 			DATE <u>10-12-99</u>		
201	RESIDENCE & CITIZENSHIP	City San Mateo	State or Foreign Country California	Country of Citizenship United States	
	POST OFFICE ADDRESS	1700 De Anza Blvd., Apt. 212	City San Mateo	State or Country California	Zip Code 94403

	FULL NAME OF INVENTOR	FIRST Name HIMANSHU	MIDDLE Initial N.	LAST Name PATEL	
INVENTOR'S SIGNATURE 			DATE: <u>10/8/99</u>		
202	RESIDENCE & CITIZENSHIP	City San Jose	State or Foreign Country California	Country of Citizenship United Kingdom	
	POST OFFICE ADDRESS	1114 Nevada Avenue	City San Jose	State or Country California	Zip Code 95125

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**POWER OF ATTORNEY
By Assignee**

ENDOTEX INTERVENTIONAL SYSTEMS, INC., assignee(s) of the application for United States Letters Patent for an improvement in **STRETCHABLE ANTI-BUCKLING COILED-SHEET STENT** by **FARHAD KHOSRAVI and HIMANSHU N. PATEL** the specification of which is

☒ filed herewith, or
☐ filed _____ having Serial No. _____.

hereby appoints as its attorneys and/or agents, with full power of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Roland N. Smoot, Reg. No. 18,718; Conrad R. Solum, Jr., Reg. No. 20,467; James W. Geriak, Reg. No. 20,233; Robert M. Taylor, Jr., Reg. No. 19,848; Samuel B. Stone, Reg. No. 19,297; Douglas E. Olson, Reg. No. 22,798; Robert E. Lyon, Reg. No. 24,171; Robert C. Weiss, Reg. No. 24,939; Richard E. Lyon, Jr., Reg. No. 26,300; John D. McConaghy, Reg. No. 26,773; William C. Steffin, Reg. No. 26,811; Coe A. Bloomberg, Reg. No. 26,605; J. Donald McCarthy, Reg. No. 25,119; John M. Benassi, Reg. No. 27,483; James H. Shalek, Reg. No. 29,749; Allan W. Jansen, Reg. No. 29,395; Robert W. Dickerson, Reg. No. 29,914; Roy L. Anderson, Reg. No. 30,240; David B. Murphy, Reg. No. 31,125; James C. Brooks, Reg. No. 29,898; Jeffrey M. Olson, Reg. No. 30,790; Steven D. Hemminger, Reg. No. 30,755; Jerrold B. Reilly, Reg. No. 32,293; Paul H. Meier, Reg. No. 32,274; John A. Rafter, Jr., Reg. No. 31,653; Kenneth H. Ohriner, Reg. No. 31,646; Mary S. Consalvi, Reg. No. 32,212; Lois M. Kwasigroch, Reg. No. 35,579; Lawrence R. LaPorte, Reg. No. 38,948; Robert C. Laurenson, Reg. No. 34,206; Carol A. Schneider, Reg. No. 34,923; Hope E. Melville, Reg. No. 34,874; Michael J. Wise, Reg. No. 34,047; Richard J. Warburg, Reg. No. 32,327; Kurt T. Mulville, Reg. No. 37,194; Theodore S. Maceiko, Reg. No. 35,593; Bruce G. Chapman, Reg. No. 33,846; and F. T. Alexandra Mahaney, Reg. No. 37,668; and William A. English, Reg. No. 42,515.

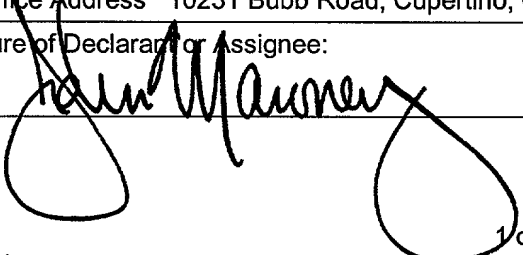
Send Correspondence to: William A. English	LYON & LYON LLP 633 W Fifth St., Suite 4700 Los Angeles, CA 90071-2066	Direct Telephone calls to: (714) 751-6606
--	---	---

I, the undersigned, declare that I have reviewed copies of the documentary evidence establishing chain of title from the inventor(s) to the assignee(s) which

☒ is filed for recordation herewith; or
☐ was recorded at Reel _____, Frame _____; or
☐ has been sent for recordation under separate cover, copy attached herewith.

The undersigned has reviewed all the documents in the chain of title of the patent applicant identified above and, to the best of the undersigned's knowledge and belief, title is in the assignee(s) identified above. Furthermore, the undersigned is empowered to sign this document on behalf of the assignee(s).

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full Name of Assignee: ENDOTEX INTERVENTIONAL SYSTEMS, INC.	
Post Office Address 10231 Bubb Road, Cupertino, California 95014	
Signature of Declarant or Assignee: 	Date: 19 October 1999

Full Name of Declarant If Other Than Assignee. JOHN MARONEY	
Title of Declarant	PRESIDENT
Address of Declarant 10231 BUBB ROAD, CUPERTINO, CALIFORNIA 95014	

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